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**HL7 Implementation Guide for CDA Release 2:  
Public Health Case Reporting, Release 1**

**US Realm**

**Based on HL7 CDA Release 2.0**

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# 1 INTRODUCTION

## 1.1 Purpose

The purpose of this implementation guide (IG) is to specify a standard for electronic submission of Public Health Case Reports (PHCR) in a Clinical Document Architecture (CDA), Release 2 format.

Common data elements found in multiple states' reportable condition forms were compiled and standardized in a project initiated in 2007 by the Centers for Disease Control and Prevention (CDC) National Center for Public Health Informatics (NCPHI) and Council of State and Territorial Epidemiologists' (CSTE) Case Report Standardization Workgroup (CRSWg) and leveraged in this project by NCPHI. This CDA for PHCR Implementation Guide will allow healthcare facilities/providers to communicate these data elements to the state and local public health departments in CDA format, an interoperable, industry-standard format.

## 1.2 Background

### 1.2.1 Public Health Case Report Standardization

In 2007, NCPHI, in collaboration with CSTE, formed the Case Report Standardization Workgroup (CRSWg). The CRSWg included members from CDC, local and state health departments, and representatives from partner organizations (e.g., Public Health Data Standards Consortium [PHDSC], National Association of County and City Health Officials [NACCHO], and Centers of Excellence in Public Health Informatics). The CRSWg objective was to address the American Health Information Community (AHIC) recommendation 2.1 on identifying Public Health Case Report (PHCR) common and condition-specific data elements.

The workgroup tasks included the following:

- Review current generic case reporting forms (e.g., confidential morbidity report, etc.), state statutes, and cross-jurisdictional administrative codes
  - Outline common data elements
  - Recommend inclusion or exclusion of common data elements
- Review current case reporting and investigation forms for anthrax, hepatitis B, tuberculosis, and tularemia
  - Outline condition-specific data elements that were consistent across jurisdictions
  - Identify data elements appropriate for initial case reporting vs. follow-up investigation
  - Recommend inclusion or exclusion of condition-specific data elements

The CRSWg was guided by the principle that a Confidential Morbidity Report (CMR) form<sup>1</sup> is the basis for identifying common data elements for clinical reporting of reportable conditions to local and/or state public health departments. The CMR forms are examples of public health regulations that require hospitals, laboratories, and physicians to report a reportable condition to local and/or state health jurisdictions.

Further, the workgroup followed these principles:

- Local and/or state jurisdictions should receive fully-identifiable data based on current state regulations for reportable conditions.<sup>2</sup>
- Primary focus was on hospital/provider reporting to local and/or state health departments.
- Secondary case reporting, such as the following, was not fully accounted for:
  - Local to local health department reporting
  - Local to state health department reporting
  - State to state health department reporting
- The minimum set of data elements were those that:
  - Are nationally applicable to public health data streams for electronic case reporting needs.
  - May overlap with other standardization efforts. One example includes recommendations for a minimum set of data elements used for Biosurveillance.<sup>3</sup>
- The template used to categorize data elements was based on the current structure of case and investigation report forms developed and in circulation by local, state, and federal public health programs. Not all variables apply to every condition.
- Common data elements and associated standardized vocabulary should apply to all forms of reporting (e.g., paper submission, web form entry, and direct extractions from electronic health records [EHRs]).
- The project identified non-condition-specific and condition-specific data elements used in public health reportable condition forms across the United States. A common core set of data elements was adopted by CSTE and included in the CSTE position statement template for placing a condition under national surveillance. The Health Information Technology Standards Panel (HITSP) Technical Committee incorporated all of the data elements identified by the workgroup into the HITSP Interoperability Specification 11 for Public Health Case Reporting.

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<sup>1</sup> CSTE. "NNDSS 2005 Queriable Database". Source: <http://www.cste.org/NNDSSHome2005.htm>. Accessed May 2007.

<sup>2</sup> *Ibid.*

<sup>3</sup> AHIC Biosurveillance Data Steering Group. "Minimum Data Set". Source: [http://www.hhs.gov/healthit/ahic/materials/meeting10/bio/BDSG\\_Minimum\\_DataSet.doc](http://www.hhs.gov/healthit/ahic/materials/meeting10/bio/BDSG_Minimum_DataSet.doc). Accessed June 2007.

Based on the findings from the workgroup, a list of four recommendations was made to CDC and CSTE:

- Cross-map each data element with the CDC Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) and assign specific value sets.
- Determine the appropriate information exchange format to model and bind the data elements.
- Determine the feasibility that each data element can be extracted from an electronic health record and transmitted electronically.
- Prioritize future review of data elements for all nationally-reportable conditions.

Thus, the findings from the CRSWg led directly to this definition of a CDA for PHCR using the identified data elements in the report.

### 1.2.2 Public Health CDA Data Element Modeling Steps

The first step in modeling the data elements in CDA R2 was to confirm and clarify their meaning and cardinality within the editorial group. After that step, the following materials were reviewed:

- HITSP/IS11
- HITSP/C80 and HITSP/C83
- PHIN Case Notification Message Mapping Guides
- Public Health Reporting and National Notification Definition Statements (09-EC-01 documents)
- HL7 Version 3 Public Health, Laboratory, and other relevant domains
- Confidentiality Morbidity Report examples
- Other CDA implementation guides
- The project developed and applied a CDC/NCPHI Terminology Strategy to determine the appropriate vocabulary terms. See [Appendix C —Terminology Principles](#)

## 1.3 Scope

The CDA for PHCR constrains CDA to meet the requirements of Public Health Case Reports for reportable conditions. Reportable conditions are those considered to be of great public health importance. Local and state agencies require that such conditions be reported when they are identified by providers or laboratories. Public Health Case Reports are reports of these conditions sent to local and state public health departments from providers. The scope of this project and this implementation guide is limited to the reporting flow from the provider to the local or state public health departments and NOT the verification process or the reporting of a confirmed condition to the national public health system (CDC). The common data elements and four condition-specific case reports were chosen by the CRSWg: anthrax, acute hepatitis B, tuberculosis, and tularemia. These are modeled in a set of modular definitions (templates) reusable across forms and conformant with design patterns established for EHRs and interoperable data exchange. These reusable pieces are documented in the format required for HL7 ballot and in a database that will ensure consistency, optimize reuse, and lay the foundation for extensibility. The database is a catalogue of the templates designed for this project.

The CRSWg identified approximately 300 common data elements associated with public health reportable condition forms across the United States. These data elements were stratified as non-condition specific and condition specific. Each element was further identified as core (should be included) vs. extended data elements (may also be included). A handful of core data elements are required to be present in all reports: the date of report, the reporter's name, the telephone and address of the reporter, and the name of the condition. This is the minimum information necessary to route the report to the appropriate public health agency/program, and to allow an investigator to contact the reporter to begin an investigation.

From the perspective of this implementation guide, required core data elements and required CDA constructs (such as document id and document creation time) are to be present in all reports. The guide defines the templates (required and optional) and indicates how those templates are organized into documents, sections, and entries to construct valid PHCR instances. Each state and/or local health department will determine which of the core data elements they require versus simply request, if any.

NOTE: The exact method by which a CDA instance is packaged and exchanged is outside the scope of the CDA standard. Please refer to section 3 of the CDA base standard [HL7 CDA, Release 2.0](#) "CDA Document Exchange in HL7 Messages". Note that the public health reporting workflow requires that the time the document is sent be captured in the exchange message.

## 1.4 HITSP Template Crosswalk

Just as CCD templates were analyzed and implied, and/or further constrained for use within this guide, HITSP C83 and C32 templates were analyzed to determine applicability. In all cases, HITSP C83 and C32 introduced additional required data elements to the templates that are beyond the scope of what CRSWg has determined to be nationally common required data elements. As stated above in section 1.3 Scope, the CRSWg project determined only five data elements to be mandatory in a Public Health Case Report.

Therefore, the related HITSP templates are not included or constrained in this version of the CDA for PHCR informative guide. In the future as the CDC and CSTE are able to determine which of these common data elements should change from a “SHOULD” or “MAY” be present status to a “SHALL” status then the HITSP templates can be revisited to determine applicability.

## 1.5 Future Work

In July 2008, CSTE engaged CDC and the Association of Public Health Laboratories (APHL) to complement the earlier work of the CRSWg to identify and promote standard medical terminologies for case reporting. This effort addresses CSTE position statements for over 70 conditions listed as nationally reportable. Like the previous effort, the new project addresses tasks in American Health Information Community (AHIC) recommendation 2.1 to specify case report criteria and identify condition-specific data elements<sup>4</sup>. In June, 2009, each of the updated position statements for 78 conditions were reviewed with 67 being approved by CSTE’s membership.

This new project is complementary to the initial work by the CRSWg that led to the development of this implementation guide. The CSTE position statements are policy documents created by CSTE members and approved by CSTE’s executive board. The policy documents are important artifacts and contain controlled vocabulary for each of the condition-specific data elements identified. The data elements in the position statement and those presented in this implementation guide will be represented consistently through a process coordinated by CDC and CSTE. Future iterations of this guide will reflect the new definitions.

## 1.6 Audience

The audience for this document includes software developers and implementers with reporting capabilities within their EHR systems, and developers and analysts in public health departments who wish to create and/or process CDA PHCR documents created according to this specification. The intended audience also includes public health domain experts.

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<sup>4</sup> 07-EC-02 and 08-EC-02 available at: <http://www.cste.org/PS/2007ps/2007psfinal/EC/07-EC-02.pdf> and <http://www.cste.org/PS/2008/2008psfinal/08-EC-02.pdf>



## 1.7 Approach

### 1.7.1 Organization of this Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see **13.01 Informative Documents** within the HL7 Governance and Operations Manual, [http://www.hl7.org/documentcenter/public/membership/HL7\\_Governance\\_and\\_Operations\\_Manual.pdf](http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf)).

#### 1.7.1.1 Templates

Templates are organized by document (see section [2 Document Templates](#)), by section (see section [3 Section Templates](#)), by clinical statements within sections (see section [4 Clinical Statement Templates](#)), and by clinical statement supporting templates (see section [5 Supporting Templates](#)). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See section [1.8 Templates Organized by Report Type](#) for a listing of templates by report type; see [Appendix A —Cited Templates](#) for a listing of templates [organized alphabetically](#) or [organized hierarchically](#).

Section [2 Document Templates](#) contains the document-level constraints for CDA PHCR documents. Here you will find the generic document-level template with constraints that apply across all PHCR case reports. In addition, condition-specific document-level templates further constrain the generic PHCR template to meet the requirements of each condition-specific case report.

Section [3 Section Templates](#) contains the section level constraints for CDA PHCR sections. Here you will find the generic section level templates with constraints that apply across all Public Health Case Reports. In addition, condition-specific section-level templates further constrain the generic section templates to meet the requirements of each condition-specific case report.

Section [4 Clinical Statement Templates](#) contains the clinical statement entries for generic data elements and for each condition-specific case report type.

Section [5 Supporting Templates](#) are always used within the context of a clinical statement template. They constrain participants, roles, and entities in the CDA Clinical Statement model.

#### 1.7.1.2 Vocabularies and Value Sets

Vocabularies recommended in this guide are primarily standard vocabularies recommended by the HITSP for use in the particular domains. In many cases these vocabularies are further constrained into value sets for use within this guide or were previously constrained into value sets by the CDC and maintained in PHIN VADS for use in the Public Health domain. PHIN VADS is the vocabulary server that this implementation guide is currently using, but PHIN VADS use is not a requirement for the CDA for PHCR. It is possible that the vocabulary hosting may shift to a different server later if so desired. In addition, while PHIN VADS is hosting the vocabulary, the contents of the dynamically bound value sets are subject to external (e.g., CSTE) governance.

PHIN VADS is based upon Whitehouse E-Gov Consolidated Health Informatics (CHI) domain recommendations and its main purpose is to distribute the vocabulary subsets that are needed for public health. PHIN VADS allows implementers to browse, search, and download the value sets associated with an implementation guide. PHIN VADS has the capability to host multiple versions of value sets and implementation guide vocabulary. PHIN VADS provides vocabulary metadata that are needed for HL7 messaging or CDA implementation. The latest version of any value set referenced in this implementation guide can be obtained from the CDC PHIN VADS [<http://phinvads.cdc.gov>].

Value set names and OIDs are summarized in a table in [Appendix B —Cited Value Sets](#). Each named value set in this summary table links to the corresponding tab in “CDA PHCR Implementation Guide Value Sets” spreadsheet containing all of the enumerated value set members and value set details as they existed at the time of IG publication. The vocabulary spreadsheet contains all the concept metadata (code system OID, name, and version) as well as references to the HITSP value set.

In some cases it was necessary to use local codes and terms while the request process for a specific code from the given vocabulary Standards Development Organization (SDO) is in progress and/or until PHIN VADS is capable of distributing the value sets with post-coordinated expressions. Principles regarding choice of vocabularies and value sets may be found in [Appendix C —Terminology Principles](#)

## 1.7.2 Use of Templates

When valued in an instance, the identifier signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

### 1.7.2.1 Originator Responsibilities

An originator can apply a `templateId` if there is a desire to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. When `templateIds` are required for conformance, they shall be asserted within the implementation guide.

### 1.7.2.2 Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to only receive CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain observation acts within a problems section, even if the entries do not have `templateIds`).

If an object does not have a `templateId`, a recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that and that are not required to be conformant by other templates.

### 1.7.3 Conventions Used in This Guide

This implementation guide is a conformance profile, as described in the [Refinement and Localization](#) section of the HL7 Version 3 standards. The base standard for this implementation guide is the [HL7 CDA, Release 2.0](#). As defined in that document, this implementation guide is both an annotation profile and a localization profile. Not every aspect of the CDA R2 is described in this guide.

#### 1.7.3.1 Explanatory Statements

As an annotation profile, portions of this implementation guide summarize or explain the base standard; therefore, not all requirements stated here are original to the implementation guide. Some originate in the base specification. Those requirements that do not add further constraints to the base standard and that can be validated through CDA.xsd may not have corresponding conformance statements.

Where no constraints are stated in this guide, PHCR CDA instances are subject to and are to be created in accordance with the base CDA R2 specification. Where, for instance, the CDA R2 specification declares an attribute to be optional and the PHCR CDA specification contains no additional constraints, that attribute remains optional for use in a PHCR CDA instance.

#### 1.7.3.2 Conformance Requirements

This implementation guide introduces a new format for CDA conformance statements. Conformance statements are grouped into and identified by the name of the template and the `templateId` and by the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint will indicate the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

**Figure 1: Template name and "conforms to" appearance**

Template name  
[<type of template>: templateId <XXXX<XX>XXX>XXX>]

Description of the template will be here .....

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name>(CodeSystem: 123.456.789)  
<XXX> Class)  
**STATIC** (CONF: <number>).  
.....

The conformance verb keyword at the start of a constraint (**SHALL**, **SHOULD**, **MAY**, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within an instance. Thus, "MAY contain 0..1" and "SHOULD contain 0..1" both allow for a document to not contain the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 1..\* as one or more present
- 0..\* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set, however, it is possible in every case to use any HL7 "null" value such as other (OTH) or unknown (UNK).

Each constraint is uniquely identified (e.g., "CONF: 605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

The keyword "specialized branch" is used within a constraint to distinguish between restrictions on a specific component vs. a restriction on a more complex pattern. For instance, one may want to say "this act can only have a single act relationship" or one may want to say "this act must have exactly one act relationship whose target act meets a given set of criteria, and this act must have exactly one act relationship whose target act meets a different set of criteria). The former constraint is a "specialized branch" constraint. An example is shown below.

**Figure 2: Template-based conformance statements example**

1. **SHALL** contain [1..1] **component/structuredBody** (CONF: 605), which
  - a. **SHOULD** contain [0..1] **component** (CONF: 914) (specialized branch), which, if present
    - i. **SHALL** contain [0..1] **CCD Social history section** (templateId: which, if present 2.16.840.1.113883.10.20.1.15) (CONF: 915).
  - b. **SHALL** contain [1..1] **component** (CONF: 606) (specialized branch), which, if present
    - i. **SHALL** contain 1..1 **PHCR Clinical information section** (templateId: 2.16.840.1.113883.10.20.15.2.1) (CONF: 607).
  - c. **SHOULD** contain [0..1] **component** (CONF: 742) (specialized branch), which, if present
    - i. **SHALL** contain [1..1] **PHCR Treatment information section** (templateId: 2.16.840.1.113883.10.20.15.2.4) (CONF: 674).
  - d. **SHOULD** contain [0..1] **component** (CONF: 673) (specialized branch), which
    - i. **SHALL** contain [1..1] **PHCR Encounters section** (templateId: 2.16.840.1.113883.10.20.15.2.2) (CONF: 1280).

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML element** styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: [http://wiki.hl7.org/index.php?title=CCD\\_Suggested\\_Enhancements](http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements). The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

**Figure 3: CCD conformance statements example**

1. The value for "Observation / @moodCode" in a problem observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
3. The value for "Observation / statusCode" in a problem observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
4. A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

### 1.7.3.3 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the [HL7 Version 3 Publishing Facilitator's Guide section 5.1.1](#). This pertinent section as reproduced below describes the terminology for expressing the stringency of a conformance statement.

HL7 adheres to ISO/IEC directive, Appendix G, as delineated in the following table.

**Table 1. Stringent Use of SHALL, SHOULD, and Other Modal Verbs**

To convey the sense of	Use the following:	
Required / mandatory	<b>SHALL</b>	<b>SHALL NOT</b>
Best practice / recommendation	<b>SHOULD</b>	<b>SHOULD NOT</b>
Acceptable / permitted	<b>MAY</b>	<b>NEED NOT</b>

Examples:

You **SHALL** clean your room before going out.

The action is REQUIRED.

You **SHALL NOT** clean your room before going out.

The action is NOT allowed.

You **SHOULD** clean your room before going out.

The action is RECOMMENDED or a BEST PRACTICE. This is a practice that is believed to be beneficial.

You **MAY** clean your room before going out.

This action is ALLOWED.

#### 1.7.3.4 XML Samples

XML samples appear in various figures in this document in a `fixed-width font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

**Figure 4: ClinicalDocument example**

```
<ClinicalDocument mins='urn:h17-org:v3'>
...
</ClinicalDocument>
```

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

#### 1.7.3.5 Contents of the Published Package

The published package contains the following files:

**Table 2: Contents of the Published Package**

Filename	Description
CDAR2_IG_PH_CASERPT_R1_I1_2009MAY.doc	This guide
PHCR_anthrax.xml	The Anthrax Public Health Case Report CDA sample file
PHCR_hep.xml	The Acute Hepatitis B Public Health Case Report CDA sample file
PHCR_tularemia.xml	The Tularemia Public Health Case Report CDA sample file
PHCR_tb.xml	The Tuberculosis Public Health Case Report CDA sample file
PHCR.xsl	The stylesheet for rendering the content of the Public Health Case Report sample documents in a web browser.
CDA_PHCR_IG_ValueSets.xls	A spreadsheet containing all value set metadata and members at the time of publication

## 1.8 Templates Organized by Report Type

The table below shows all of the Public Health Case Report templates organized by report type. This table is placed prior to the template descriptions and conformance statements to provide the reader with an understanding of various groupings and organization of the templates that are used in the generic report, and the acute hepatitis B, the tularemia, and the tuberculosis public health case reports.

**Table 3: Templates Organized by Report Type**

Template OID	Type	Template Title
<b>2.16.840.1.113883.10.20.15</b>	<b>document</b>	<a href="#">Public Health Case Report CDA R2 template root</a>
2.16.840.1.113883.10.20.1.6	section	<a href="#">CCD Immunizations section</a>
2.16.840.1.113883.10.20.1.24	entry	<a href="#">CCD Medication activity</a>
2.16.840.1.113883.10.20.1.46	entry	<a href="#">CCD Medication series number observation</a>
2.16.840.1.113883.10.20.1.47	entry	<a href="#">CCD Medication status observation</a>
2.16.840.1.113883.10.20.15.2.1	section	<a href="#">PHCR Clinical information section</a>
2.16.840.1.113883.10.20.15.3.42	entry	<a href="#">Patient condition – alive</a>
2.16.840.1.113883.10.20.15.3.17	entry	<a href="#">Patient condition – deceased</a>
2.16.840.1.113883.10.20.15.3.54	entry	<a href="#">PHCR Case observation</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.53	entry	<a href="#">PHCR Signs and symptoms</a>
2.16.840.1.113883.10.20.15.2.2	section	<a href="#">PHCR Encounters section</a>
2.16.840.1.113883.10.20.1.21	entry	<a href="#">CCD Encounter activity</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
2.16.840.1.113883.10.20.15.2.3	section	<a href="#">PHCR Relevant diagnostic tests and/or laboratory data section</a>
2.16.840.1.113883.10.20.15.3.5	entry	<a href="#">Imaging observation</a>
2.16.840.1.113883.10.20.15.3.58	entry	<a href="#">PHCR Result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.59	entry	<a href="#">PHCR Result organizer</a>
2.16.840.1.113883.10.20.15.3.58	entry	<a href="#">PHCR Result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.2.22	section	<a href="#">PHCR Social history section</a>
2.16.840.1.113883.10.20.15.3.3	entry	<a href="#">Geotemporal history observation</a>
2.16.840.1.113883.10.20.15.3.6	entry	<a href="#">Most recent time arrived in USA observation</a>
2.16.840.1.113883.10.20.15.3.7	entry	<a href="#">Occupation observation</a>
2.16.840.1.113883.10.20.15.3.8	entry	<a href="#">Pregnancy observation</a>
2.16.840.1.113883.10.20.15.3.1	entry	<a href="#">Estimated date of delivery</a>
2.16.840.1.113883.10.20.15.3.9	entry	<a href="#">Race observation</a>
2.16.840.1.113883.10.20.15.2.4	section	<a href="#">PHCR Treatment information section</a>
2.16.840.1.113883.10.20.15.3.57	entry	<a href="#">PHCR Therapeutic regimen</a>
2.16.840.1.113883.10.20.15.3.55	entry	<a href="#">PHCR Treatment given</a>

Template OID	Type	Template Title
2.16.840.1.113883.10.20.15.3.56	entry	<a href="#">PHCR Treatment not given</a>
<b>2.16.840.1.113883.10.20.15.1.2</b>	<b>document</b>	Acute Hepatitis B PHCR CDA R2 report
2.16.840.1.113883.10.20.15.2.12	section	<a href="#">Acute hepatitis B PHCR clinical information section</a>
2.16.840.1.113883.10.20.15.3.30	entry	<a href="#">Acute hepatitis B case observation</a>
2.16.840.1.113883.10.20.15.3.22	entry	<a href="#">Acute hepatitis B signs and symptoms</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.31	entry	<a href="#">Acute hepatitis B risk associated procedure</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
2.16.840.1.113883.10.20.15.3.42	entry	<a href="#">Patient condition – alive</a>
2.16.840.1.113883.10.20.15.3.17	entry	<a href="#">Patient condition – deceased</a>
2.16.840.1.113883.10.20.15.3.33	entry	<a href="#">STD history observation</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.32	entry	<a href="#">Viral hepatitis history observation</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.2.9	section	<a href="#">Acute hepatitis B PHCR immunization section</a>
2.16.840.1.113883.10.20.15.3.25	entry	<a href="#">Acute hepatitis B immunization activity</a>
2.16.840.1.113883.10.20.1.46	entry	<a href="#">CCD Medication series number observation</a>
2.16.840.1.113883.10.20.1.47	entry	<a href="#">CCD Medication status observation</a>
2.16.840.1.113883.10.20.15.3.24	supporting	<a href="#">Acute hepatitis B immunization product</a>
2.16.840.1.113883.10.20.15.2.13	section	Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section
2.16.840.1.113883.10.20.15.3.34	entry	<a href="#">Acute hepatitis B result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.5	entry	<a href="#">Imaging observation</a>
2.16.840.1.113883.10.20.15.2.11	section	<a href="#">Acute hepatitis B PHCR social history section</a>
2.16.840.1.113883.10.20.15.3.26	entry	<a href="#">Acute hepatitis B actual blood and/or body fluid exposure observation</a>
2.16.840.1.113883.10.20.15.3.27	entry	<a href="#">Acute hepatitis B possible exposure location and type</a>
2.16.840.1.113883.10.20.15.3.28	entry	<a href="#">Acute hepatitis B socio-behavioral boolean risk factor</a>
2.16.840.1.113883.10.20.15.3.3	entry	<a href="#">Geotemporal history observation</a>



Template OID	Type	Template Title
2.16.840.1.113883.10.20.15.3.29	entry	<a href="#">Job related body fluid exposure risk frequency</a>
2.16.840.1.113883.10.20.15.3.6	entry	<a href="#">Most recent time arrived in USA observation</a>
2.16.840.1.113883.10.20.15.3.7	entry	<a href="#">Occupation observation</a>
2.16.840.1.113883.10.20.15.3.8	entry	<a href="#">Pregnancy observation</a>
2.16.840.1.113883.10.20.15.3.1	entry	<a href="#">Estimated date of delivery</a>
2.16.840.1.113883.10.20.15.3.9	entry	<a href="#">Race observation</a>
2.16.840.1.113883.10.20.15.2.10	section	<a href="#">Acute hepatitis B PHCR treatment information section</a>
2.16.840.1.113883.10.20.15.3.23	entry	<a href="#">Acute hepatitis B therapeutic regimen</a>
2.16.840.1.113883.10.20.15.2.2	section	<a href="#">PHCR Encounters section</a>
2.16.840.1.113883.10.20.1.21	entry	<a href="#">CCD Encounter activity</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
<b>2.16.840.1.113883.10.20.15.1.3</b>	<b>document</b>	<a href="#">Anthrax PHCR CDA R2 report</a>
2.16.840.1.113883.10.20.15.2.15	section	<a href="#">Anthrax PHCR clinical information section</a>
2.16.840.1.113883.10.20.15.3.36	entry	<a href="#">Anthrax case observation</a>
2.16.840.1.113883.10.20.15.3.35	entry	<a href="#">Anthrax signs and symptoms</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.42	entry	<a href="#">Patient condition – alive</a>
2.16.840.1.113883.10.20.15.3.17	entry	<a href="#">Patient condition – deceased</a>
2.16.840.1.113883.10.20.15.2.16	section	<a href="#">Anthrax PHCR relevant diagnostic tests and/or laboratory data section</a>
2.16.840.1.113883.10.20.15.3.39	entry	<a href="#">Anthrax result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.40	entry	<a href="#">Anthrax result organizer</a>
2.16.840.1.113883.10.20.15.3.39	entry	<a href="#">Anthrax result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.5	entry	<a href="#">Imaging observation</a>
2.16.840.1.113883.10.20.15.2.17	section	<a href="#">Anthrax PHCR social history section</a>
2.16.840.1.113883.10.20.15.3.41	entry	<a href="#">Anthrax possible exposure location and type</a>
2.16.840.1.113883.10.20.15.3.3	entry	<a href="#">Geotemporal history observation</a>
2.16.840.1.113883.10.20.15.3.6	entry	<a href="#">Most recent time arrived in USA observation</a>
2.16.840.1.113883.10.20.15.3.7	entry	<a href="#">Occupation observation</a>

Template OID	Type	Template Title
2.16.840.1.113883.10.20.15.3.8	entry	<a href="#">Pregnancy observation</a>
2.16.840.1.113883.10.20.15.3.1	entry	<a href="#">Estimated date of delivery</a>
2.16.840.1.113883.10.20.15.3.9	entry	<a href="#">Race observation</a>
2.16.840.1.113883.10.20.15.2.14	section	<a href="#">Anthrax PHCR treatment information section</a>
2.16.840.1.113883.10.20.15.3.37	entry	<a href="#">Anthrax therapeutic regimen</a>
2.16.840.1.113883.10.20.15.3.38	entry	<a href="#">Anthrax treatment given</a>
2.16.840.1.113883.10.20.15.3.49	entry	<a href="#">Anthrax treatment not given</a>
2.16.840.1.113883.10.20.15.2.2	section	<a href="#">PHCR Encounters section</a>
2.16.840.1.113883.10.20.1.21	entry	<a href="#">CCD Encounter activity</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
<b>2.16.840.1.113883.10.20.15.1.1</b>	<b>document</b>	<a href="#">Tuberculosis PHCR CDA R2 report</a>
2.16.840.1.113883.10.20.15.2.2	section	<a href="#">PHCR Encounters section</a>
2.16.840.1.113883.10.20.1.21	entry	<a href="#">CCD Encounter activity</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
2.16.840.1.113883.10.20.15.2.5	section	<a href="#">Tuberculosis PHCR clinical information section</a>
2.16.840.1.113883.10.20.15.3.42	entry	<a href="#">Patient condition – alive</a>
2.16.840.1.113883.10.20.15.3.17	entry	<a href="#">Patient condition – deceased</a>
2.16.840.1.113883.10.20.15.3.11	entry	<a href="#">Tuberculosis case observation</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.14	entry	<a href="#">Tuberculosis signs and symptoms</a>
2.16.840.1.113883.10.20.15.2.6	section	<a href="#">Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section</a>
2.16.840.1.113883.10.20.15.3.5	entry	<a href="#">Imaging observation</a>
2.16.840.1.113883.10.20.15.3.13	entry	<a href="#">Tuberculosis result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.21	entry	<a href="#">Tuberculosis result organizer</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.13	entry	<a href="#">Tuberculosis result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.2.7	section	<a href="#">Tuberculosis PHCR social history section</a>
2.16.840.1.113883.10.20.15.3.3	entry	<a href="#">Geotemporal history observation</a>
2.16.840.1.113883.10.20.15.3.4	entry	<a href="#">HIV status observation</a>
2.16.840.1.113883.10.20.15.3.6	entry	<a href="#">Most recent time arrived in USA observation</a>
2.16.840.1.113883.10.20.15.3.7	entry	<a href="#">Occupation observation</a>

Template OID	Type	Template Title
2.16.840.1.113883.10.20.15.3.8	entry	<a href="#">Pregnancy observation</a>
2.16.840.1.113883.10.20.15.3.1	entry	<a href="#">Estimated date of delivery</a>
2.16.840.1.113883.10.20.15.3.9	entry	<a href="#">Race observation</a>
2.16.840.1.113883.10.20.15.3.12	entry	<a href="#">Tuberculosis possible exposure location</a>
2.16.840.1.113883.10.20.15.3.15	entry	<a href="#">Tuberculosis socio-behavioral boolean risk factor</a>
2.16.840.1.113883.10.20.15.2.8	section	<a href="#">Tuberculosis PHCR treatment information section</a>
2.16.840.1.113883.10.20.15.3.18	entry	<a href="#">Tuberculosis therapeutic regimen</a>
2.16.840.1.113883.10.20.15.3.16	entry	<a href="#">Tuberculosis treatment given</a>
2.16.840.1.113883.10.20.15.3.19	entry	<a href="#">Tuberculosis treatment not given</a>
<b>2.16.840.1.113883.10.20.15.1.4</b>	<b>document</b>	<a href="#">Tularemia PHCR CDA R2 report</a>
2.16.840.1.113883.10.20.15.2.2	section	<a href="#">PHCR Encounters section</a>
2.16.840.1.113883.10.20.1.21	entry	<a href="#">CCD Encounter activity</a>
2.16.840.1.113883.10.20.1.45	supporting	<a href="#">CCD Location participation</a>
2.16.840.1.113883.10.20.15.2.19	section	<a href="#">Tularemia PHCR clinical information section</a>
2.16.840.1.113883.10.20.15.3.42	entry	<a href="#">Patient condition – alive</a>
2.16.840.1.113883.10.20.15.3.17	entry	<a href="#">Patient condition – deceased</a>
2.16.840.1.113883.10.20.15.3.46	entry	<a href="#">Tularemia case observation</a>
2.16.840.1.113883.10.20.1.50	entry	<a href="#">CCD Problem status observation</a>
2.16.840.1.113883.10.20.15.3.44	entry	<a href="#">Location of lesion observation</a>
2.16.840.1.113883.10.20.15.3.45	entry	<a href="#">Tularemia signs and symptoms</a>
2.16.840.1.113883.10.20.15.2.21	section	<a href="#">Tularemia PHCR relevant diagnostic tests and/or laboratory data section</a>
2.16.840.1.113883.10.20.15.3.5	entry	<a href="#">Imaging observation</a>
2.16.840.1.113883.10.20.15.3.51	entry	<a href="#">Tularemia result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.3.52	entry	<a href="#">Tularemia result organizer</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.51	entry	<a href="#">Tularemia result observation</a>
2.16.840.1.113883.10.20.15.3.2	entry	<a href="#">Specimen collection procedure</a>
2.16.840.1.113883.10.20.15.3.10	entry	<a href="#">Susceptibility result</a>
2.16.840.1.113883.10.20.15.2.18	section	<a href="#">Tularemia PHCR social history section</a>
2.16.840.1.113883.10.20.15.3.3	entry	<a href="#">Geotemporal history observation</a>
2.16.840.1.113883.10.20.15.3.6	entry	<a href="#">Most recent time arrived in USA observation</a>
2.16.840.1.113883.10.20.15.3.7	entry	<a href="#">Occupation observation</a>
2.16.840.1.113883.10.20.15.3.8	entry	<a href="#">Pregnancy observation</a>

Template OID	Type	Template Title
2.16.840.1.113883.10.20.15.3.1	entry	<a href="#">Estimated date of delivery</a>
2.16.840.1.113883.10.20.15.3.9	entry	<a href="#">Race observation</a>
2.16.840.1.113883.10.20.15.3.43	entry	<a href="#">Tularemia possible exposure location and type</a>
2.16.840.1.113883.10.20.15.2.20	section	<a href="#">Tularemia PHCR treatment information section</a>
2.16.840.1.113883.10.20.15.3.48	entry	<a href="#">Tularemia therapeutic regimen</a>
2.16.840.1.113883.10.20.15.3.47	entry	<a href="#">Tularemia treatment given</a>
2.16.840.1.113883.10.20.15.3.50	entry	<a href="#">Tularemia treatment not given</a>

## 2 DOCUMENT TEMPLATES

This section contains the document-level constraints for CDA PHCR documents. Here you will find the generic document-level template with constraints that apply across all PHCR case reports. In addition, condition-specific document-level templates further constrain the generic PHCR template to meet the requirements of each condition - specific case report.

### 2.1 Public Health Case Report CDA R2 template root

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15]

The CDA for PHCR constrains CDA to express the data elements identified by the CSTE CRSWg. This PHCR CDA R2 template root defines the data elements that belong in the header of a CDA document and prescribes the sections that belong in a generic PHCR. The person who completes a PHCR is referred to as the reporter. This reporter is represented with the CDA document author. This reporter is often the infection control professional at an institution but may be any individual at a healthcare organization who is designated to do so. The CDA legalAuthenticator is the verifier who officially confirms the accuracy of the document. In the public health workflow this legal authenticator may be the infection control professional who is also the author/reporter of the reportable condition or may be another individual designated to authenticate the report by the organization. It is required that the name and contact information of the reporter and the legal authenticator be provided. Most sections and data elements are optional. The clinical information section is required and contains data elements determined by the CRSWg to be required consistently when reporting a case to the state/local public health department. Note that state and/or local health departments may require additional data elements, beyond those identified by the CSTE CRSWg as required consistently across jurisdictions. Reporters must adhere to local and state rules applicable to their location. NOTE: A generic PHCR document may be sent where there is a case of a reportable condition for which no specific PHCR document template has been defined. In such a case, the report shall adhere to this template.

1. **SHALL** contain [1..1] **code/@code="55751-2" Public Health Case Report** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:546)
2. **SHALL** contain [1..1] **recordTarget** (CONF:547), which
  - a. **SHALL** contain [1..1] **patientRole** (CONF:548), which
    - i. **SHALL** contain [1..\*] **id** (CONF:549)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:550)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:551)
    - iv. **SHOULD** contain [0..1] **patient** (CONF:552), which if present
      1. **SHOULD** contain [0..\*] **name** (CONF:553)
      2. **SHOULD** contain [0..1] **administrativeGenderCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3) **DYNAMIC** (CONF:554)
      3. **SHOULD** contain [0..1] **birthTime** (CONF:555)

4. **SHOULD** contain [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.837 Ethnicity group **DYNAMIC** (CONF:556)
  5. **SHOULD** contain [0..1] **birthplace/place**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3200 Birth Country **DYNAMIC** (CONF:557)
3. **SHALL** contain [1..\*] **author** (CONF:1853), which
  - a. **SHALL** contain [1..1] **time** (CONF:560)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:561), which
    - i. **SHALL** contain [1..\*] **id** (CONF:562)
    - ii. **SHALL** contain [1..1] **addr** (CONF:563)
    - iii. **SHALL** contain [1..1] **telecom** (CONF:564)
    - iv. **SHALL** contain [1..1] **assignedPerson/name** (CONF:565)
4. The custodian of a public health case report **SHALL** be the reporting organization (CONF:1616).
5. **SHALL** contain [1..1] **legalAuthenticator** (CONF:1854), which
  - a. **SHALL** contain [1..1] **time** (CONF:1855)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1856), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1857)
    - ii. **SHALL** contain [1..1] **addr** (CONF:1858)
    - iii. **SHALL** contain [1..1] **telecom** (CONF:1859)
    - iv. **SHALL** contain [1..1] **assignedPerson/name** (CONF:1860)
6. **SHALL** contain [1..1] **component/structuredBody** (CONF:605), which
  - a. **SHOULD** contain [0..1] **component** (CONF:914) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Social history section**  
(templateId:2.16.840.1.113883.10.20.15.2.22) (CONF:915)
  - b. **SHALL** contain [1..1] **component** (CONF:606) (specialized branch), which
    - i. **SHALL** contain [1..1] **PHCR Clinical information section**  
(templateId:2.16.840.1.113883.10.20.15.2.1) (CONF:607)
  - c. **SHOULD** contain [0..1] **component** (CONF:742) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Treatment information section**  
(templateId:2.16.840.1.113883.10.20.15.2.4) (CONF:674)
  - d. **SHOULD** contain [0..1] **component** (CONF:673) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Encounters section**  
(templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:609)
  - e. **SHOULD** contain [0..1] **component** (CONF:608) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Relevant diagnostic tests and/or laboratory data section**  
(templateId:2.16.840.1.113883.10.20.15.2.3) (CONF:743)
  - f. **MAY** contain [0..1] **component** (CONF:1285) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **CCD Immunizations section**  
(templateId:2.16.840.1.113883.10.20.1.6) (CONF:1286)
7. Where a Public Health Case Report CDA R2 document contains any of the section or clinical statement templates defined in this implementation guide, such section or clinical statement **SHALL** include a templateId/@root valued with the corresponding template's identifier. (CONF:2017).

8. **SHALL** contain [1..1] **code/@code="55751-2" Public Health Case Report** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:546)
9. **SHALL** contain [1..1] **recordTarget** (CONF:547), which
  - a. **SHALL** contain [1..1] **patientRole** (CONF:548), which
    - i. **SHALL** contain [1..\*] **id** (CONF:549)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:550)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:551)
    - iv. **SHOULD** contain [0..1] **patient** (CONF:552), which if present
      1. **SHOULD** contain [0..\*] **name** (CONF:553)
      2. **SHOULD** contain [0..1] **administrativeGenderCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3) **DYNAMIC** (CONF:554)
      3. **SHOULD** contain [0..1] **birthTime** (CONF:555)
      4. **SHOULD** contain [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.837 Ethnicity group **DYNAMIC** (CONF:556)
      5. **SHOULD** contain [0..1] **birthplace/place**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3200 Birth Country **DYNAMIC** (CONF:557)
10. **SHALL** contain [1..\*] **author** (CONF:1853), which
  - a. **SHALL** contain [1..1] **time** (CONF:560)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:561), which
    - i. **SHALL** contain [1..\*] **id** (CONF:562)
    - ii. **SHALL** contain [1..1] **addr** (CONF:563)
    - iii. **SHALL** contain [1..1] **telecom** (CONF:564)
    - iv. **SHALL** contain [1..1] **assignedPerson/name** (CONF:565)
11. The custodian of a public health case report **SHALL** be the reporting organization (CONF:1616).
12. **SHALL** contain [1..1] **legalAuthenticator** (CONF:1854), which
  - a. **SHALL** contain [1..1] **time** (CONF:1855)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1856), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1857)
    - ii. **SHALL** contain [1..1] **addr** (CONF:1858)
    - iii. **SHALL** contain [1..1] **telecom** (CONF:1859)
    - iv. **SHALL** contain [1..1] **assignedPerson/name** (CONF:1860)
13. **SHALL** contain [1..1] **component/structuredBody** (CONF:605), which
  - a. **SHALL** contain [1..1] **component** (CONF:606) (specialized branch), which
    - i. **SHALL** contain [1..1] **PHCR Clinical information section** (templateId:2.16.840.1.113883.10.20.15.2.1) (CONF:607)
  - b. **SHOULD** contain [0..1] **component** (CONF:608) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Relevant diagnostic tests and/or laboratory data section** (templateId:2.16.840.1.113883.10.20.15.2.3) (CONF:743)
  - c. **SHOULD** contain [0..1] **component** (CONF:673) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Encounters section** (templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:609)
  - d. **SHOULD** contain [0..1] **component** (CONF:742) (specialized branch), which if present

- i. **SHALL** contain [1..1] **PHCR Treatment information section** (templateId:2.16.840.1.113883.10.20.15.2.4) (CONF:674)
  - e. **SHOULD** contain [0..1] **component** (CONF:914) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Social history section** (templateId:2.16.840.1.113883.10.20.15.2.22) (CONF:915)
  - f. **MAY** contain [0..1] **component** (CONF:1285) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **CCD Immunizations section** (templateId:2.16.840.1.113883.10.20.1.6) (CONF:1286)
14. Where a Public Health Case Report CDA R2 document contains any of the section or clinical statement templates defined in this implementation guide, such section or clinical statement **SHALL** include a templateId/@root valued with the corresponding template's identifier. (CONF:2017).

### 2.1.1 Acute Hepatitis B PHCR CDA R2 report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.2]

The CDA for acute hepatitis B PHCR constrains CDA to express the data elements identified by the CRSWg as specific to a hepatitis B case report. Acute hepatitis B is a liver disease caused by the hepatitis B virus (HBV). Acute hepatitis B occurs shortly after exposure to the virus.<sup>5</sup>

1. Conforms to Public Health Case Report CDA R2 template root Template (templateId: 2.16.840.1.113883.10.20.15).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.1.2" (CONF:1268)
3. **SHALL** contain [1..1] **title**="Public Health Case Report - Acute Hepatitis B" (CONF:1269)
4. **SHALL** contain [1..1] **component/structuredBody** (CONF:1270), which
  - a. **SHOULD** contain [0..1] **component** (CONF:1271) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Acute hepatitis B PHCR social history section** (templateId:2.16.840.1.113883.10.20.15.2.11) (CONF:1272)
  - b. **SHOULD** contain [0..1] **component** (CONF:1273) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Acute hepatitis B PHCR immunization section** (templateId:2.16.840.1.113883.10.20.15.2.9) (CONF:1274)
  - c. **SHALL** contain [1..1] **component** (CONF:1275) (specialized branch), which
    - i. **SHALL** contain [1..1] **Acute hepatitis B PHCR clinical Information section** (templateId:2.16.840.1.113883.10.20.15.2.12) (CONF:1276)
  - d. **SHOULD** contain [0..1] **component** (CONF:1277) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Acute hepatitis B PHCR treatment information section** (templateId:2.16.840.1.113883.10.20.15.2.10) (CONF:1278)
  - e. **SHOULD** contain [0..1] **component** (CONF:1279) (specialized branch), which if present

<sup>5</sup> Centers for Disease Control and Prevention Diseases and conditions information page: <http://www.cdc.gov/hepatitis/HBV.htm>



- i. **SHALL** contain [1..1] **PHCR Encounters section**  
(templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:1280)
- f. **SHOULD** contain [0..1] **component** (CONF:1281) (specialized branch), which if present
  - i. **SHALL** contain [1..1] **Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section**  
(templateId:2.16.840.1.113883.10.20.15.2.13) (CONF:1282)

See Figure 5: Generic PHCR CDA R2 report example for an example of a generic PHCR report.

## 2.1.2 Anthrax PHCR CDA R2 report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.3]

The CDA for Anthrax Public Health Case Report constrains CDA to express the data elements identified by the CRSWg as specific to a case report of anthrax. Anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. Anthrax most commonly occurs in wild and domestic mammalian species (cattle, sheep, goats, camels, antelopes, and other herbivores), but it can also occur in humans when they are exposed to infected animals or to tissue from infected animals or when anthrax spores are used as a bioterrorist weapon.<sup>6</sup>

1. Conforms to Public Health Case Report CDA R2 template root Template (templateId: 2.16.840.1.113883.10.20.15).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.1.3" (CONF:1533)
3. **SHALL** contain [1..1] **title**="Public Health Case Report - Anthrax" (CONF:1534)
4. **SHALL** contain [1..1] **component/structuredBody** (CONF:1535), which
  - a. **SHOULD** contain [0..1] **component** (CONF:1536) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Anthrax PHCR social history section**  
(templateId:2.16.840.1.113883.10.20.15.2.17) (CONF:1537)
  - b. **SHALL** contain [1..1] **component** (CONF:1538) (specialized branch), which
    - i. **SHALL** contain [1..1] **Anthrax PHCR clinical information section**  
(templateId:2.16.840.1.113883.10.20.15.2.15) (CONF:1539)
  - c. **SHOULD** contain [0..1] **component** (CONF:1540) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Anthrax PHCR treatment information section**  
(templateId:2.16.840.1.113883.10.20.15.2.14) (CONF:1541)
  - d. **SHOULD** contain [0..1] **component** (CONF:1542) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Encounters section**  
(templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:1543)
  - e. **SHOULD** contain [0..1] **component** (CONF:1544) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Anthrax PHCR relevant diagnostic tests and/or laboratory data section**  
(templateId:2.16.840.1.113883.10.20.15.2.16) (CONF:1545)

<sup>6</sup> CDC Emergency Preparedness and Response webpage:  
<http://www.bt.cdc.gov/agent/anthrax/faq/>

See Figure 5: Generic PHCR CDA R2 report example for an example of a generic PHCR report.

### 2.1.3 Tuberculosis PHCR CDA R2 report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.1]

The CDA for Tuberculosis Public Health Case Report constrains CDA to express the data elements identified by the CRSWg as specific to a case report of tuberculosis. Tuberculosis (TB) is a contagious and potentially life-threatening infectious disease caused by a bacterium called *Mycobacterium tuberculosis*. The tuberculosis bacteria are spread from person to person through the air.<sup>7</sup>

1. Conforms to Public Health Case Report CDA R2 template root Template (templateId: 2.16.840.1.113883.10.20.15).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.1.1" (CONF:568)
3. **SHALL** contain [1..1] **title**="Public Health Case Report - Tuberculosis" (CONF:569)
4. **SHALL** contain [1..1] **component/structuredBody** (CONF:610) (specialized branch), which
  - a. **SHOULD** contain [0..1] **component** (CONF:916) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tuberculosis PHCR social history section** (templateId:2.16.840.1.113883.10.20.15.2.7) (CONF:917)
  - b. **SHALL** contain [1..1] **component** (CONF:611) (specialized branch), which
    - i. **SHALL** contain [1..1] **Tuberculosis PHCR clinical information section** (templateId:2.16.840.1.113883.10.20.15.2.5) (CONF:612)
  - c. **SHOULD** contain [0..1] **component** (CONF:675) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tuberculosis PHCR treatment information section** (templateId:2.16.840.1.113883.10.20.15.2.8) (CONF:676)
  - d. **SHOULD** contain [0..1] **component** (CONF:690) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Encounters section** (templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:687)
  - e. **SHOULD** contain [0..1] **component** (CONF:744) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section** (templateId:2.16.840.1.113883.10.20.15.2.6) (CONF:745)

See Figure 5: Generic PHCR CDA R2 report example for an example of a generic PHCR report.

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<sup>7</sup> The CDC National Institute for Safety and Health Information webpage:  
<http://www.cdc.gov/niosh/topics/tb/>

## 2.1.4 Tularemia PHCR CDA R2 report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.4]

The CDA for Tularemia Public Health Case Report constrains CDA to express the data elements identified by the CRSWg as specific to a case report of tularemia. Tularemia is a disease caused by the bacterium *Francisella tularensis*. Tularemia is typically found in animals, especially rodents, rabbits, and hares. Tularemia is usually a rural disease and has been reported in all U.S. states except Hawaii. *Francisella tularensis* is highly infectious. A small number of bacteria (10-50 organisms) can cause disease. If *Francisella tularensis* were used as a bioweapon, the bacteria would likely be made airborne so they could be inhaled. People who inhale the bacteria can experience severe respiratory illness, including life-threatening pneumonia and systemic infection, if they are not treated.<sup>8</sup>

1. Conforms to Public Health Case Report CDA R2 template root Template (templateId: 2.16.840.1.113883.10.20.15).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.1.4" (CONF:1839)
3. **SHALL** contain [1..1] **title**="Public Health Case Report - Tularemia" (CONF:1840)
4. **SHALL** contain [1..1] **component/structuredBody** (CONF:1841), which
  - a. **SHOULD** contain [0..1] **component** (CONF:1842) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tularemia PHCR social history section** (templateId:2.16.840.1.113883.10.20.15.2.18) (CONF:1843)
  - b. **SHALL** contain [1..1] **component** (CONF:1844) (specialized branch), which
    - i. **SHALL** contain [1..1] **Tularemia PHCR clinical information section** (templateId:2.16.840.1.113883.10.20.15.2.19) (CONF:1845)
  - c. **SHOULD** contain [0..1] **component** (CONF:1846) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tularemia PHCR treatment information section** (templateId:2.16.840.1.113883.10.20.15.2.20) (CONF:1847)
  - d. **SHOULD** contain [0..1] **component** (CONF:1848) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **PHCR Encounters section** (templateId:2.16.840.1.113883.10.20.15.2.2) (CONF:1849)
  - e. **SHOULD** contain [0..1] **component** (CONF:1850) (specialized branch), which if present
    - i. **SHALL** contain [1..1] **Tularemia PHCR relevant diagnostic tests and/or laboratory data section** (templateId:2.16.840.1.113883.10.20.15.2.21) (CONF:1851)

---

<sup>8</sup> CDC Emergency Preparedness and Response webpage:  
<http://www.bt.cdc.gov/agent/tularemia/faq.asp>

**Figure 5: Generic PHCR CDA R2 report example**

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
  xmlns:voc="urn:hl7-org:v3/voc"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">

<!-- CDA Header -->

  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="X-DISEASE TEMPLATEID" />
  <!-- DISEASE Report template root -->
  <id root="db734647-fc99-424c-a864-7e3cda82e703" />
  <code code="55751-2" codeSystem="2.16.840.1.113883.6.1"
    displayName=" Public Health Case report" />
  <title>Public Health Case Report - DISEASE</title>
  <effectiveTime value="20090110130000+0500" />
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" />
  <languageCode code="en-US" />
  <recordTarget>
    <patientRole>
      <id extension="996-756-495" root="2.16.840.1.113883.19.5" />
      <addr>
        ...
      <telecom value="tel:+1-888-888-8888;ext=9999" />

      <patient>
        <name use="L">
          ...
        </name>
        <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" />
        <birthTime value="19830924" />
        <ethnicGroupCode code="2135-2" codeSystem="2.16.840.1.113883.6.238"
          displayName="HISPANIC OR LATINO" />
        <birthplace>
          <place>
            <addr>
              <country>USA</country>
            </addr>
          </place>
        </birthplace>
      </patient>
      <providerOrganization>
        <id root="2.16.840.1.113883.19.5" />
        <name>Good Health Hospital</name>
      </providerOrganization>
    </patientRole>
  </recordTarget>
  <author>
    <time value="20090110130000+0500" />
    <assignedAuthor>
      <id extension="33333334" root="2.16.840.1.113883.19.5" />
      <addr>
        ...
      <telecom value="tel:+1-888-888-8888;ext=9998" />
      <assignedPerson>
        <name>
```

```

    ...
</author>
<custodian>
    ...
</custodian>
<legalAuthenticator>
    ...
    <addr/>
    ...
    <telecom value="tel:+1-888-888-8888;ext=9998" />
    <assignedPerson>
        <name>
            ...
        </name>
    </assignedPerson>
</legalAuthenticator>

<!-- CDA Body -->

<component>
    <structuredBody>

        <component>
            <section>
                <templateId root="X-DISEASE CLIN INFO TEMPLATEID" />
                <code code="55752-0" codeSystem="2.16.840.1.113883.6.1"
                    displayName="Clinical Information" />
                <title>Social history</title>
                ...
            </section>
        </component>

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

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

```

## 3 SECTION TEMPLATES

This section contains the section level constraints for CDA PHCR sections. Here you will find the generic section level templates with constraints that apply across all Public Health Case Reports. In addition, condition-specific section-level templates further constrain the generic section templates to meet the requirements of each condition-specific case report.

### 3.1 CCD Encounters section

[section: templateId 2.16.840.1.113883.10.20.1.3]

The CCD encounters section is used to list and describe any healthcare encounters pertinent to the patient's current health status or historical health history. An encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section may contain all encounters for the time period being summarized, but should include notable encounters.

1. The encounters section SHALL contain Section / code. (CONF: 593).
2. The value for "Section / code" SHALL be "46240-8" "History of encounters" 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 594).
3. The encounters section SHALL contain Section / title. (CONF: 595).
4. Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "encounters". (CONF: 596).

#### 3.1.1 PHCR Encounters section

[section: templateId 2.16.840.1.113883.10.20.15.2.2]

The PHCR encounters section defines the code and title for all PHCR encounters sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. Conforms to CCD Encounters section Template (templateId: 2.16.840.1.113883.10.20.1.3).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.2" (CONF:597)
3. **SHALL** contain [1..1] **title**="Encounters" (CONF:598)
4. **SHALL** contain [1..1] **text** (CONF:599)
5. **SHALL** contain [1..\*] **entry** (CONF:602) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:603)
  - b. **SHALL** contain [1..1] **CCD Encounter activity** (templateId:2.16.840.1.113883.10.20.1.21) (CONF:604)

**Figure 6: PHCR encounters section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.2" />
  <code code="46240-8" codeSystem="2.16.840.1.113883.6.1" />
  <title>Encounters</title>
  ...
</section>
```

## 3.2 CCD Immunizations section

[section; templateId 2.16.840.1.113883.10.20.1.6]

The immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the immunization section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

1. The Immunizations section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34). (CONF: 1012).
2. The immunizations section SHALL contain Section / code. (CONF: 1008).
3. The value for "Section / code" SHALL be "11369-6" "History of immunizations" 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 1009).
4. The immunizations section SHALL contain Section / title. (CONF: 1010).
5. Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "immunization". (CONF: 1011).

### 3.2.1 Acute hepatitis B PHCR immunization section

[section: templateId 2.16.840.1.113883.10.20.15.2.9]

The hepatitis B immunization section template differs from the CCD section template clinical statement constraints only in that it constrains the section entries and subentries to contain the hepatitis B immunization manufactured product template, which constrains the manufacturedMaterial codes to a specific hepatitis B CDC CVX value set.

1. Conforms to CCD Immunizations section Template (templateId: 2.16.840.1.113883.10.20.1.6).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.9" (CONF:1057)
3. **SHALL** contain [1..\*] **entry** (CONF:1054) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1055)
  - b. **SHALL** contain [1..1] **Acute hepatitis B immunization activity** (templateId:2.16.840.1.113883.10.20.15.3.25) (CONF:1056)

**Figure 7: Acute hepatitis B PHCR immunization section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.9" />
  <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
    displayName="History of immunization" />
  <title>History of immunization</title>
  ...
  <entry typeCode="DRIV">
    <!-- Acute hepatitis B immunization activity -->
    ...
  </entry>
  ...
</section>
```

### 3.3 CCD Results section

[section: templateId 2.16.840.1.113883.10.20.1.14]

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends. Lab results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient, submitted to the lab. Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echo. Procedure results are typically generated by a clinician wanting to provide more granular information about component observations made during the performance of a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

1. The Results section SHALL contain a narrative block, and SHOULD contain clinical statements. Clinical statements SHOULD include one or more result organizers (templateId 2.16.840.1.113883.10.20.1.32), each of which SHALL contain one or more result observations (templateId 2.16.840.1.113883.10.20.1.31). (CONF: 1962).
2. The result section SHALL contain Section / code. (CONF: 1963).
3. The value for "Section / code" SHALL be "30954-2" "Relevant diagnostic tests and/or laboratory data" 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 1964).
4. The results section SHALL contain Section / title. (CONF: 1965).
5. Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "results". (CONF: 1966).



### 3.3.1 PHCR Relevant diagnostic tests and/or laboratory data section

[section: templateId 2.16.840.1.113883.10.20.15.2.3]

The PHCR relevant diagnostic tests and/or laboratory data section defines the code and title for all PHCR relevant diagnostic tests and/or laboratory data sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. Conforms to CCD Results section Template (templateId: 2.16.840.1.113883.10.20.1.14).
2. **SHALL** contain [1..1] **code/@code**="30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:735)
3. **SHALL** contain [1..1] **title**="Relevant diagnostic tests and/or laboratory data" (CONF:736)
4. **SHALL** contain [1..1] **text** (CONF:737)
5. **MAY** contain [0..\*] **entry** (CONF:854) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:855)
  - b. **SHALL** contain [1..1] **PHCR Result organizer** (templateId:2.16.840.1.113883.10.20.15.3.59) (CONF:856)
6. **SHOULD** contain [0..\*] **entry** (CONF:2011) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2012)
  - b. **SHALL** contain [1..1] **PHCR Result observation** (templateId:2.16.840.1.113883.10.20.15.3.58) (CONF:2013)
7. **MAY** contain [0..\*] **entry** (CONF:2014) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2015)
  - b. **SHALL** contain [1..1] **Imaging observation** (templateId:2.16.840.1.113883.10.20.15.3.5) (CONF:2016)

#### 3.3.1.1 Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section

[section: templateId 2.16.840.1.113883.10.20.15.2.13]

The acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges. In addition, it captures the name of organization where the specimens were collected.

1. Conforms to PHCR Relevant diagnostic tests and/or laboratory data section Template (templateId: 2.16.840.1.113883.10.20.15.2.3).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.13" (CONF:1258)
3. **SHOULD** contain [0..\*] **entry** (CONF:1259) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1260)
  - b. **SHALL** contain [1..1] **Acute hepatitis B result observation** (templateId:2.16.840.1.113883.10.20.15.3.34) (CONF:1261)

4. **MAY** contain [0..\*] **entry** (CONF:1265) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1266)
  - b. **SHALL** contain [1..1] **Imaging observation** (templateId:2.16.840.1.113883.10.20.15.3.5) (CONF:1267)

**Figure 8: Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.13" />
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Relevant diagnostic tests and/or laboratory data" />
  <title>Relevant diagnostic tests and/or laboratory data</title>
  ...
</section>
```

### 3.3.1.2 Anthrax PHCR relevant diagnostic tests and/or laboratory data section

[section: templateId 2.16.840.1.113883.10.20.15.2.16]

The anthrax PHCR relevant diagnostic tests and/or laboratory data section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges and susceptibility results. In addition, it captures the name of the organization where the specimens were collected.

1. Conforms to PHCR Relevant diagnostic tests and/or laboratory data section Template (templateId: 2.16.840.1.113883.10.20.15.2.3).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.16" (CONF:1440)
3. **MAY** contain [0..\*] **entry** (CONF:1441) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1442)
  - b. **SHALL** contain [1..1] **Anthrax result organizer** (templateId:2.16.840.1.113883.10.20.15.3.40) (CONF:1443)
4. **SHOULD** contain [0..\*] **entry** (CONF:1530) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1531)
  - b. **SHALL** contain [1..1] **Anthrax result observation** (templateId:2.16.840.1.113883.10.20.15.3.39) (CONF:1532)
5. **MAY** contain [0..\*] **entry** (CONF:1444) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1445)
  - b. **SHALL** contain [1..1] **Imaging observation** (templateId:2.16.840.1.113883.10.20.15.3.5) (CONF:1446)

**Figure 9: PHCR relevant diagnostic tests and/or laboratory data section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.16"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Relevant diagnostic tests and/or laboratory data"/>
  <title>Relevant diagnostic tests and/or laboratory data</title>
  ...
</section>
```

### 3.3.1.3 Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section [section: templateId 2.16.840.1.113883.10.20.15.2.6]

The tuberculosis PHCR relevant diagnostic tests and/or laboratory data section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges and susceptibility results. In addition, it captures the name of organization where the specimens were collected.

1. Conforms to PHCR Relevant diagnostic tests and/or laboratory data section Template (templateId: 2.16.840.1.113883.10.20.15.2.3).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.6" (CONF:738)
3. **MAY** contain [0..\*] **entry** (CONF:978) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:979)
  - b. **SHALL** contain [1..1] **Tuberculosis result organizer** (templateId:2.16.840.1.113883.10.20.15.3.21) (CONF:980)
4. **SHOULD** contain [0..\*] **entry** (CONF:739) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:740)
  - b. **SHALL** contain [1..1] **Tuberculosis result observation** (templateId:2.16.840.1.113883.10.20.15.3.13) (CONF:741)
5. **MAY** contain [0..\*] **entry** (CONF:857) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:858)
  - b. **SHALL** contain [1..1] **Imaging observation** (templateId:2.16.840.1.113883.10.20.15.3.5) (CONF:859)

**Figure 10: Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.6" />
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Relevant diagnostic tests and/or laboratory data" />
  <title>Relevant diagnostic tests and/or laboratory data</title>
  ...
</section>
```

### 3.3.1.4 Tularemia PHCR relevant diagnostic tests and/or laboratory data section

[section: templateId 2.16.840.1.113883.10.20.15.2.21]

The tularemia PHCR relevant diagnostic tests and/or laboratory data section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges and susceptibility results. In addition, it captures the name of the organization where the specimens were collected.

1. Conforms to PHCR Relevant diagnostic tests and/or laboratory data section Template (templateId: 2.16.840.1.113883.10.20.15.2.3).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.21" (CONF:1829)
3. **MAY** contain [0..\*] **entry** (CONF:1830) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1831)
  - b. **SHALL** contain [1..1] **Tularemia result organizer** (templateId:2.16.840.1.113883.10.20.15.3.52) (CONF:1832)
4. **SHOULD** contain [0..\*] **entry** (CONF:1833) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1834)
  - b. **SHALL** contain [1..1] **Tularemia result observation** (templateId:2.16.840.1.113883.10.20.15.3.51) (CONF:1835)
5. **MAY** contain [0..\*] **entry** (CONF:1836) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1837)
  - b. **SHALL** contain [1..1] **Imaging observation** (templateId:2.16.840.1.113883.10.20.15.3.5) (CONF:1838)

**Figure 11: Tularemia PHCR relevant diagnostic tests and/or laboratory data section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.21" />
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Relevant diagnostic tests and/or laboratory data" />
  <title>Relevant diagnostic tests and/or laboratory data</title>
  ...
</section>
```

## 3.4 CCD Social history section

[section: templateId 2.16.840.1.113883.10.20.1.15]

This section contains data defining the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

1. The social history section SHALL contain Section / code. (CONF: 875).
2. The value for "Section / code" SHALL be "29762-2" "Social history" 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 876).
3. The social history section SHALL contain Section / title. (CONF: 877).
4. Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "social history". (CONF: 882).

### 3.4.1 PHCR Social history section

[section: templateId 2.16.840.1.113883.10.20.15.2.22]

The PHCR social history section template contains data defining the patients occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the case report.

1. Conforms to CCD Social history section Template (templateId: 2.16.840.1.113883.10.20.1.15).
2. **SHALL** contain [1..1] **code/@code="29762-2" Social history** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:1894)
3. **SHALL** contain [1..1] **title="Social History"** (CONF:1895)
4. **SHALL** contain [1..1] **text** (CONF:1896)
5. **SHOULD** contain [0..\*] **entry** (CONF:1897) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1898)
  - b. **SHALL** contain [1..1] **Geotemporal history observation** (templateId:2.16.840.1.113883.10.20.15.3.3) (CONF:1899)
6. **SHOULD** contain [0..1] **entry** (CONF:1900) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1901)
  - b. **SHALL** contain [1..1] **Most recent time arrived in USA observation** (templateId:2.16.840.1.113883.10.20.15.3.6) (CONF:1902)
7. **SHOULD** contain [0..\*] **entry** (CONF:1903) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1904)
  - b. **SHALL** contain [1..1] **Race observation** (templateId:2.16.840.1.113883.10.20.15.3.9) (CONF:1905)
8. **SHOULD** contain [0..\*] **entry** (CONF:1906) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1907)
  - b. **SHALL** contain [1..1] **Occupation observation** (templateId:2.16.840.1.113883.10.20.15.3.7) (CONF:1908)
9. **MAY** contain [0..\*] **entry** (CONF:1909) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1910)
  - b. **SHALL** contain [1..1] **Pregnancy observation** (templateId:2.16.840.1.113883.10.20.15.3.8) (CONF:1911)

### 3.4.1.1 Acute hepatitis B PHCR social history section

[section: templateId 2.16.840.1.113883.10.20.15.2.11]

The acute hepatitis B PHCR social history section template contains data defining the patients occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the hepatitis B case report.

1. Conforms to PHCR Social history section Template (templateId: 2.16.840.1.113883.10.20.15.2.22).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.11"** (CONF:1115)
3. **SHOULD** contain [0..\*] **entry** (CONF:1116) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1117)
  - b. **SHALL** contain [1..1] **Race observation** (templateId:2.16.840.1.113883.10.20.15.3.9) (CONF:1118)
4. **MAY** contain [0..\*] **entry** (CONF:1119) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1120)
  - b. **SHALL** contain [1..1] **Pregnancy observation** (templateId:2.16.840.1.113883.10.20.15.3.8) (CONF:1121)
5. **SHOULD** contain [0..\*] **entry** (CONF:1122) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1123)
  - b. **SHALL** contain [1..1] **Occupation observation** (templateId:2.16.840.1.113883.10.20.15.3.7) (CONF:1124)
6. **SHOULD** contain [0..\*] **entry** (CONF:1125) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1126)
  - b. **SHALL** contain [1..1] **Job related body fluid exposure risk frequency** (templateId:2.16.840.1.113883.10.20.15.3.29) (CONF:1127)
7. **SHOULD** contain [0..\*] **entry** (CONF:1128) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1129)
  - b. **SHALL** contain [1..1] **Acute hepatitis B socio-behavioral boolean risk factor** (templateId:2.16.840.1.113883.10.20.15.3.28) (CONF:1130)
8. **SHOULD** contain [0..\*] **entry** (CONF:1134) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1135)
  - b. **SHALL** contain [1..1] **Geotemporal history observation** (templateId:2.16.840.1.113883.10.20.15.3.3) (CONF:1136)
9. **MAY** contain [0..1] **entry** (CONF:1143) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1144)
  - b. **SHALL** contain [1..1] **Most recent time arrived in USA observation** (templateId:2.16.840.1.113883.10.20.15.3.6) (CONF:1145)
10. **MAY** contain [0..\*] **entry** (CONF:1137) (specialized branch), which if present

- a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1141)
  - b. **SHALL** contain [1..1] **Acute hepatitis B actual blood and/or body fluid exposure observation** (templateId:2.16.840.1.113883.10.20.15.3.26) (CONF:1142)
11. **MAY** contain [0..\*] **entry** (CONF:1140) (specialized branch), which if present
- a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1138)
  - b. **SHALL** contain [1..1] **Acute hepatitis B possible exposure location and type** (templateId:2.16.840.1.113883.10.20.15.3.27) (CONF:1139)

**Figure 12: Acute hepatitis B PHCR social history section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.11" />
  <!-- Social History Section template (Including risk factors) -->
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Social history" />
  <title>Social history</title>
  ...
</section>
```

#### 3.4.1.2 Anthrax PHCR social history section

[section: templateId 2.16.840.1.113883.10.20.15.2.17]

The anthrax PHCR social history section template contains data defining the patients occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the anthrax case report.

1. Conforms to PHCR Social history section Template (templateId: 2.16.840.1.113883.10.20.15.2.22).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.17"** (CONF:1499)
3. **SHOULD** contain [0..\*] **entry** (CONF:1500) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1501)
  - b. **SHALL** contain [1..1] **Race observation** (templateId:2.16.840.1.113883.10.20.15.3.9) (CONF:1502)
4. **MAY** contain [0..\*] **entry** (CONF:1503) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1504)
  - b. **SHALL** contain [1..1] **Pregnancy observation** (templateId:2.16.840.1.113883.10.20.15.3.8) (CONF:1505)
5. **SHOULD** contain [0..\*] **entry** (CONF:1506) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1507)

- b. **SHALL** contain [1..1] **Occupation observation**  
(templateId:2.16.840.1.113883.10.20.15.3.7) (CONF:1508)
- 6. **SHOULD** contain [0..\*] **entry** (CONF:1512) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1513)
  - b. **SHALL** contain [1..1] **Geotemporal history observation**  
(templateId:2.16.840.1.113883.10.20.15.3.3) (CONF:1520)
- 7. **MAY** contain [0..1] **entry** (CONF:1527) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1528)
  - b. **SHALL** contain [1..1] **Most recent time arrived in USA observation**  
(templateId:2.16.840.1.113883.10.20.15.3.6) (CONF:1529)
- 8. **MAY** contain [0..\*] **entry** (CONF:1521) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1522)
  - b. **SHALL** contain [1..1] **Anthrax possible exposure location and type**  
(templateId:2.16.840.1.113883.10.20.15.3.41) (CONF:1523)

**Figure 13: Anthrax PHCR social history section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.17"/>
  <!-- Social History Section template (Including risk factors) -->
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Social history"/>
  <title>Social history</title>
  ...
</section>
```

### 3.4.1.3 Tuberculosis PHCR social history section

[section: templateId 2.16.840.1.113883.10.20.15.2.7]

The tuberculosis social history section template contains data defining the patients occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the tuberculosis case report.

- 1. Conforms to PHCR Social history section Template (templateId: 2.16.840.1.113883.10.20.15.2.22).
- 2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.7"** (CONF:878)
- 3. **SHOULD** contain [0..\*] **entry** (CONF:879) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:880)
  - b. **SHALL** contain [1..1] **Race observation**  
(templateId:2.16.840.1.113883.10.20.15.3.9) (CONF:881)
- 4. **MAY** contain [0..\*] **entry** (CONF:893) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:894)



- b. **SHALL** contain [1..1] **Pregnancy observation**  
(templateId:2.16.840.1.113883.10.20.15.3.8) (CONF:895)
- 5. **SHOULD** contain [0..\*] **entry** (CONF:896) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:897)
  - b. **SHALL** contain [1..1] **Occupation observation**  
(templateId:2.16.840.1.113883.10.20.15.3.7) (CONF:898)
- 6. **SHOULD** contain [0..\*] **entry** (CONF:899) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:900)
  - b. **SHALL** contain [1..1] **Tuberculosis possible exposure location**  
(templateId:2.16.840.1.113883.10.20.15.3.12) (CONF:901)
- 7. **SHOULD** contain [0..1] **entry** (CONF:902) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:903)
  - b. **SHALL** contain [1..1] **HIV status observation**  
(templateId:2.16.840.1.113883.10.20.15.3.4) (CONF:904)
- 8. **SHOULD** contain [0..\*] **entry** (CONF:905) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:906)
  - b. **SHALL** contain [1..1] **Tuberculosis socio-behavioral boolean risk factor**  
(templateId:2.16.840.1.113883.10.20.15.3.15) (CONF:907)
- 9. **SHOULD** contain [0..\*] **entry** (CONF:908) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:909)
  - b. **SHALL** contain [1..1] **Geotemporal history observation**  
(templateId:2.16.840.1.113883.10.20.15.3.3) (CONF:910)
- 10. **MAY** contain [0..1] **entry** (CONF:911) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:912)
  - b. **SHALL** contain [1..1] **Most recent time arrived in USA observation**  
(templateId:2.16.840.1.113883.10.20.15.3.6) (CONF:913)

**Figure 14: Tuberculosis PHCR social history section example**

```

<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.7" />
  <!-- Social History Section template (Including risk factors) -->
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Social history" />
  <title>Social history</title>
  ...
</section>

```

#### 3.4.1.4 Tularemia PHCR social history section

[section: templateId 2.16.840.1.113883.10.20.15.2.18]

The tularemia PHCR social history section template contains data defining the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the tularemia case report.

1. Conforms to PHCR Social history section Template (templateId: 2.16.840.1.113883.10.20.15.2.22).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.18"** (CONF:1653)
3. **SHOULD** contain [0..\*] **entry** (CONF:1654) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1655)
  - b. **SHALL** contain [1..1] **Race observation** (templateId:2.16.840.1.113883.10.20.15.3.9) (CONF:1656)
4. **MAY** contain [0..\*] **entry** (CONF:1657) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1658)
  - b. **SHALL** contain [1..1] **Pregnancy observation** (templateId:2.16.840.1.113883.10.20.15.3.8) (CONF:1659)
5. **SHOULD** contain [0..\*] **entry** (CONF:1660) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1661)
  - b. **SHALL** contain [1..1] **Occupation observation** (templateId:2.16.840.1.113883.10.20.15.3.7) (CONF:1662)
6. **SHOULD** contain [0..\*] **entry** (CONF:1663) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1664)
  - b. **SHALL** contain [1..1] **Geotemporal history observation** (templateId:2.16.840.1.113883.10.20.15.3.3) (CONF:1665)
7. **MAY** contain [0..1] **entry** (CONF:1666) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1667)
  - b. **SHALL** contain [1..1] **Most recent time arrived in USA observation** (templateId:2.16.840.1.113883.10.20.15.3.6) (CONF:1668)
8. **MAY** contain [0..\*] **entry** (CONF:1669) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1670)
  - b. **SHALL** contain [1..1] **Tularemia possible exposure location and type** (templateId:2.16.840.1.113883.10.20.15.3.43) (CONF:1671)

**Figure 15: Tularemia PHCR social history section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.18" />
  <!-- Social History Section template (Including risk factors) -->
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Social history" />
  <title>Social history</title>
  ...
</section>
```

### 3.5 PHCR Clinical information section

[section: templateId 2.16.840.1.113883.10.20.15.2.1]

The PHCR clinical information section defines the code and title for all PHCR clinical information sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. **SHALL** contain [1..1] **code/@code="55752-0" Clinical Information** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:540)
2. **SHALL** contain [1..1] **title="Clinical Information"** (CONF:541)
3. **SHALL** contain [1..1] **text** (CONF:542)
4. **SHALL** contain [1..1] **entry** (CONF:1891) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1892)
  - b. **SHALL** contain [1..1] **PHCR case observation** (templateId:2.16.840.1.113883.10.20.15.3.54) (CONF:1893)
5. **MAY** contain [0..1] **entry** (CONF:1912) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1913)
  - b. **SHALL** contain [1..1] **Patient condition - deceased** (templateId:2.16.840.1.113883.10.20.15.3.17) (CONF:1914)
6. **MAY** contain [0..1] **entry** (CONF:1915) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1916)
  - b. **SHALL** contain [1..1] **Patient condition - alive** (templateId:2.16.840.1.113883.10.20.15.3.42) (CONF:1917)
7. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition - deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1918).

### 3.5.1 Acute hepatitis B PHCR clinical information section

[section: templateId 2.16.840.1.113883.10.20.15.2.12]

The acute hepatitis B clinical information section contains the acute hepatitis B case observation clinical statement template, a history of procedures associated with risk for hepatitis B, a history of other viral hepatitis diagnoses, and a history of sexually transmitted disease (STD) diagnoses, including whether or not the STD was treated. It also contains the templates representing whether the subject of the case report was alive or deceased at the time of the report and if deceased, if the disease being reported caused the death. Both templates (patient condition alive and patient condition - deceased) should not be present together.

1. Conforms to PHCR Clinical information section Template (templateId: 2.16.840.1.113883.10.20.15.2.1).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.12"** (CONF:1218)
3. **SHALL** contain [1..1] **entry** (CONF:1228) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1220)
  - b. **SHALL** contain [1..1] **Acute hepatitis B case observation** (templateId:2.16.840.1.113883.10.20.15.3.30) (CONF:1221)
4. **SHOULD** contain [0..\*] **entry** (CONF:1225) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1223)
  - b. **SHALL** contain [1..1] **Acute hepatitis B risk associated procedure** (templateId:2.16.840.1.113883.10.20.15.3.31) (CONF:1224)
5. **SHOULD** contain [0..\*] **entry** (CONF:1222) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1226)
  - b. **SHALL** contain [1..1] **Viral hepatitis history observation** (templateId:2.16.840.1.113883.10.20.15.3.32) (CONF:1227)
6. **SHOULD** contain [0..\*] **entry** (CONF:1219) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1229)
  - b. **SHALL** contain [1..1] **STD history observation** (templateId:2.16.840.1.113883.10.20.15.3.33) (CONF:1230)
7. **MAY** contain [0..1] **entry** (CONF:1598) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1599)
  - b. **SHALL** contain [1..1] **Patient condition - deceased** (templateId:2.16.840.1.113883.10.20.15.3.17) (CONF:1600)
8. **MAY** contain [0..1] **entry** (CONF:1601) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1602)
  - b. **SHALL** contain [1..1] **Patient condition - alive** (templateId:2.16.840.1.113883.10.20.15.3.42) (CONF:1603)

9. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition - deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1716).

**Figure 16: Acute hepatitis B PHCR clinical information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.12" />
  <!-- Section template -->
  <code code="55752-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Clinical Information" />
  <title>Clinical Information</title>
  ...
  <entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <!-- Acute Hep B case observation -->
      ...
    </observation>
  </entry>
  ...
</section>
```

### 3.5.2 Anthrax PHCR clinical information section

[section: templateId 2.16.840.1.113883.10.20.15.2.15]

The anthrax clinical information section contains the anthrax case observation clinical statement template. It also contains the templates representing whether the subject of the case report was alive or deceased at the time of the report and, if deceased, if the disease being reported caused the death. Both templates (patient condition alive and patient condition - deceased) should not be present together.

1. Conforms to PHCR Clinical information section Template (templateId: 2.16.840.1.113883.10.20.15.2.1).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.15"** (CONF:1360)
3. **SHALL** contain [1..1] **entry** (CONF:1361) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1362)
  - b. **SHALL** contain [1..1] **Anthrax case observation** (templateId:2.16.840.1.113883.10.20.15.3.36) (CONF:1363)
4. **MAY** contain [0..1] **entry** (CONF:1604) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1605)
  - b. **SHALL** contain [1..1] **Patient condition - deceased** (templateId:2.16.840.1.113883.10.20.15.3.17) (CONF:1606)
5. **MAY** contain [0..1] **entry** (CONF:1607) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1608)
  - b. **SHALL** contain [1..1] **Patient condition - alive** (templateId:2.16.840.1.113883.10.20.15.3.42) (CONF:1609)

6. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition - deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1715).

**Figure 17: Anthrax PHCR clinical information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.15"/>
  <code code="55752-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Clinical Information"/>
  <title>Clinical Information</title>
  ...
  <entry typeCode="DRIV">
    <!-- Anthrax case observation -->
    <observation classCode="OBS" moodCode="EVN">
      ...
    </observation>
  </entry>
  ...
</section>
```

### 3.5.3 Tuberculosis PHCR clinical information section

[section: templateId 2.16.840.1.113883.10.20.15.2.5]

The tuberculosis clinical information section contains the tuberculosis case observation clinical statement template. It also contains the templates representing whether the subject of the case report was alive or deceased at the time of the report and, if deceased, if the disease being reported caused the death. Both templates (patient condition alive and patient condition - deceased) should not be present together.

1. Conforms to PHCR Clinical information section Template (templateId: 2.16.840.1.113883.10.20.15.2.1).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.5" (CONF:567)
3. **SHALL** contain [1..1] **entry** (CONF:543) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:544)
  - b. **SHALL** contain [1..1] **Tuberculosis case observation** (templateId:2.16.840.1.113883.10.20.15.3.11) (CONF:545)
4. **SHOULD** contain [0..1] **entry** (CONF:1610) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1611)
  - b. **SHALL** contain [1..1] **Patient condition - deceased** (templateId:2.16.840.1.113883.10.20.15.3.17) (CONF:1612)
5. **SHOULD** contain [0..1] **entry** (CONF:1613) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1614)
  - b. **SHALL** contain [1..1] **Patient condition - alive** (templateId:2.16.840.1.113883.10.20.15.3.42) (CONF:1615)

6. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition - deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1714).

**Figure 18: Tuberculosis PHCR clinical information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.5" />
  <code code="55752-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Clinical Information" />
  <title>Clinical Information</title>
  ...
  <entry typeCode="DRIV">
    <!-- TB case observation -->
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.15.3.11"/>
      ...
    </observation>
  </entry>
  ...
</section>
```

### 3.5.4 Tularemia PHCR clinical information section

[section: templateId 2.16.840.1.113883.10.20.15.2.19]

The tularemia clinical information section contains the tularemia case observation clinical statement template. It also contains the templates representing whether the subject of the case report was alive or deceased at the time of the report and, if deceased, if the disease being reported caused the death. Both templates (patient condition alive and patient condition - deceased) should not be present together.

1. Conforms to PHCR Clinical information section Template (templateId: 2.16.840.1.113883.10.20.15.2.1).
2. **SHALL** contain [1..1] **templateId/@root="2.16.840.1.113883.10.20.15.2.19"** (CONF:1717)
3. **SHALL** contain [1..1] **entry** (CONF:1718) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1719)
  - b. **SHALL** contain [1..1] **Tularemia case observation** (templateId:2.16.840.1.113883.10.20.15.3.46) (CONF:1720)
4. **MAY** contain [0..1] **entry** (CONF:1721) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1722)
  - b. **SHALL** contain [1..1] **Patient condition - deceased** (templateId:2.16.840.1.113883.10.20.15.3.17) (CONF:1723)
5. **MAY** contain [0..1] **entry** (CONF:1724) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="DRIV"** *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1725)

- b. **SHALL** contain [1..1] **Patient condition - alive**  
(templateId:2.16.840.1.113883.10.20.15.3.42) (CONF:1726)
6. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition - deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1727).

**Figure 19: Tularemia PHCR clinical information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.19" />
  <code code="55752-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Clinical Information" />
  <title>Clinical Information</title>
  ...
  <entry typeCode="DRIV">
    <!--Tularemia case observation -->
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.15.3.46"/>
      ...
    </observation>
  </entry>
  ...
</section>
```

### 3.6 PHCR Treatment information section

[section: templateId 2.16.840.1.113883.10.20.15.2.4]

The PHCR treatment information section defines the code and title for all PHCR treatment information sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. **SHALL** contain [1..1] **code/@code="55753-8" Treatment Information** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:663)
2. **SHALL** contain [1..1] **title="Treatment Information"** (CONF:664)
3. **SHALL** contain [1..1] **text** (CONF:665)
4. **SHALL** contain [1..1] **entry** (CONF:1959) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="DRIV" Is derived from** (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1960)
  - b. **SHALL** contain [1..1] **PHCR Therapeutic regimen**  
(templateId:2.16.840.1.113883.10.20.15.3.57) (CONF:1961)

#### 3.6.1 Acute hepatitis B PHCR treatment information section

[section: templateId 2.16.840.1.113883.10.20.15.2.10]

The acute hepatitis B PHCR treatment information section is for recording treatments, other than immunizations, that have been provided to the subject of the case report. These may be medications or any other treatments the reporter feels pertinent to include in the report. Immunizations will be recorded in the immunization section.



1. Conforms to PHCR Treatment information section Template (templateId: 2.16.840.1.113883.10.20.15.2.4).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.10" (CONF:1061)
3. **SHALL** contain [1..1] **entry** (CONF:1062) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1063)
  - b. **SHALL** contain [1..1] **Acute hepatitis B therapeutic regimen** (templateId:2.16.840.1.113883.10.20.15.3.23) (CONF:1064)

**Figure 20: Acute hepatitis B PHCR treatment information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.10" />
  <code code="55753-8" codeSystem="2.16.840.1.113883.6.1"
    displayName="Treatment Information" />
  <title>Treatment Information</title>
  ...
</section>
```

### 3.6.2 Anthrax PHCR treatment information section

[section: templateId 2.16.840.1.113883.10.20.15.2.14]

The anthrax PHCR treatment section is for recording treatments that have been provided to the subject of the case report. These may be medications or any other treatments the reporter feels pertinent to include in the report. Some workflows may require reporting of typical treatments that were NOT prescribed.

1. Conforms to PHCR Treatment information section Template (templateId: 2.16.840.1.113883.10.20.15.2.4).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.14" (CONF:1356)
3. **SHALL** contain [1..1] **entry** (CONF:1357) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1358)
  - b. **SHALL** contain [1..1] **Anthrax therapeutic regimen** (templateId:2.16.840.1.113883.10.20.15.3.37) (CONF:1359)

**Figure 21: Anthrax PHCR treatment information section example**

```
section>
  <templateId root="2.16.840.1.113883.10.20.15.2.14"/>
  <code code="55753-8" codeSystem="2.16.840.1.113883.6.1"
    displayName="Treatment Information"/>
  <title>Treatment Information</title>
  ...
</section>
```

### 3.6.3 Tuberculosis PHCR treatment information section

[section: templateId 2.16.840.1.113883.10.20.15.2.8]

The tuberculosis PHCR treatment section is for recording treatments that have been provided to the subject of the case report. These may be medications or any other treatments the reporter feels pertinent to include in the report. Some workflows may require reporting of typical treatments that were NOT prescribed.

1. Conforms to PHCR Treatment information section Template (templateId: 2.16.840.1.113883.10.20.15.2.4).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.8" (CONF:666)
3. **SHALL** contain [1..1] **entry** (CONF:667) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:668)
  - b. **SHALL** contain [1..1] **Tuberculosis therapeutic regimen** (templateId:2.16.840.1.113883.10.20.15.3.18) (CONF:669)

**Figure 22: Tuberculosis PHCR treatment information section example**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.15.2.8" />
  <code code="55753-8" codeSystem="2.16.840.1.113883.6.1"
    displayName="Treatment Information" />
  <title>Treatment Information</title>
  ...
  <entry typeCode="DRIV">
    <!-- TB therapeutic regimen -->
    <act classCode="ACT" moodCode="EVN" negationInd="false">
      <templateId root="2.16.840.1.113883.10.20.15.3.18"/>
      ...
    </act>
  </entry>
</section>
```

### 3.6.4 Tularemia PHCR treatment information section

[section: templateId 2.16.840.1.113883.10.20.15.2.20]

The tularemia PHCR treatment section is for recording treatments that have been provided to the subject of the case report. These may be medications or any other treatments the reporter feels pertinent to include in the report. Some workflows may require reporting of typical treatments that were NOT prescribed.

1. Conforms to PHCR Treatment information section Template (templateId: 2.16.840.1.113883.10.20.15.2.4).
2. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.2.20" (CONF:1781)
3. **SHALL** contain [1..1] **entry** (CONF:1782) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="DRIV" *Is derived from* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1783)
  - b. **SHALL** contain [1..1] **Tularemia therapeutic regimen** (templateId:2.16.840.1.113883.10.20.15.3.48) (CONF:1784)

**Figure 23: Tularemia PHCR treatment information section example**

```
section>
  <templateId root="2.16.840.1.113883.10.20.15.2.20"/>
  <code code="55753-8" codeSystem="2.16.840.1.113883.6.1"
    displayName="Treatment Information"/>
  <title>Treatment Information</title>
  ...
</section>
```

## 4 CLINICAL STATEMENT TEMPLATES

This section of the implementation guide details the clinical statement entries referenced in the above sections for each disease case report type.

### 4.1 *Acute hepatitis B actual blood and/or body fluid exposure observation*

[observation: templateId 2.16.840.1.113883.10.20.15.3.26]

This clinical statement represents the type of actual blood or body fluid exposure the subject of the case report encountered. This template is different than the acute hepatitis B possible exposure location and type template that identifies the way subject of the case report MAY have been exposed to the virus. This template is stating the definite instances of blood or body fluid exposure the subject of the case report experienced. It is NOT inferring that the exposure to the blood or body fluid equals an exposure to the hepatitis B virus. The value data type in this entry is unconstrained as it may be an integer or a boolean true/false or other value data type as needed if the value set expands.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1065)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1066)
3. **SHALL** contain [1..\*] **id** (CONF:1071)
4. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3224 Blood or body fluid exposure event **DYNAMIC** (CONF:1067)
5. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1068)
6. **MAY** contain [0..1] **effectiveTime** (CONF:1069)
7. **SHALL** contain [1..1] **value** (CONF:1070)

**Figure 24: Acute hepatitis B actual blood and/or body fluid exposure observation example**

```
<entry typeCode="DRIV">
  <!-- Hep B Actual Blood and/or body fluid exposure observation-->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.26" />
    <id nullFlavor="NI"/>
    <code code="55213-3" codeSystem="2.16.840.1.113883.6.1"
      displayName="Number of male sexual partners in 6
        months before symptom onset" />
    <statusCode code="completed" />
    <value xsi:type="INT" value="2" />
  </observation>
</entry>
```

## 4.2 Acute hepatitis B possible exposure location and type

[act: templateId 2.16.840.1.113883.10.20.15.3.27]

This clinical statement represents locations where it is possible that an exposure to hepatitis B may have occurred. It can also represent type of exposure (contact) that took place. These are simply locations and types of contact that have been identified by public health departments as associated with higher risk of coming into contact with the hepatitis B virus. The reporter is NOT inferring that the patient was definitively exposed in this manner or at this location. If known, the likely exposure date or date range should be sent. The possible exposure location should capture the address and the type of location.

1. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1072)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1073)
3. **SHALL** contain [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1076), which
  - a. **SHALL** contain [1..1] **qualifier** (CONF:1077) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="246090004" *Associated finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1078)
    - ii. **SHALL** contain [1..1] **value/@code**="281638009" *Hepatitis B contact* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1079)
  - b. **SHALL** contain [1..1] **qualifier** (CONF:1080) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="408729009" *Finding context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1081)
    - ii. **SHALL** contain [1..1] **value/@code**="410590009" *Known possible* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1082)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1075)
5. **SHALL** contain [1..\*] **participant** (CONF:1083) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1084)
  - b. **SHOULD** contain [0..1] **time** (CONF:1085)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1086), which
    - i. **SHALL** contain [1..1] **@classCode**="LOCE" *Located entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1087)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:1088)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:1089)
    - iv. **SHOULD** contain [0..1] **playingEntity** (CONF:1090), which if present
      1. **SHALL** contain [1..1] **@classCode**="PLC" *Place* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1091)
      2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3209 Exposure Location **DYNAMIC** (CONF:1092)
6. **SHOULD** contain [0..\*] **participant** (CONF:1565) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DIR" *Direct target* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1566)

- b. **SHOULD** contain [0..1] **time** (CONF:1567)
- c. **SHALL** contain [1..1] **participantRole** (CONF:1568), which
  - i. **SHALL** contain [1..1] **@classCode**="EXPR" *Exposed entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1569)
  - ii. **SHALL** contain [1..1] **scopingEntity** (CONF:1852)
  - iii. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3210 Contact Type (Hepatitis B) **DYNAMIC** (CONF:1572)

**Figure 25: Acute hepatitis B possible exposure location and type example**

```
<entry typeCode="DRIV">
  <!-- HEP B Possible exposure location and type-->
  <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.27" />
    <code code="413350009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Finding with explicit context">
      <qualifier>
        <name code="246090004" displayName="Associated finding"/>
        <value code="281638009" displayName="Hepatitis B contact"/>
      </qualifier>
      <qualifier>
        <name code="408729009" displayName="Finding context"/>
        <value code="410590009" displayName="Known possible"/>
      </qualifier>
    </code>
    <statusCode code="completed"/>
    <participant typeCode="LOC">
      <time>
        <low value="20040704"/>
        <high value="20040707"/>
      </time>
      <participantRole classCode="LOCE">
        <addr>
          <streetAddressLine>1001 Lone Tree Rd</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <playingEntity classCode="PLC">
          <code code="PHC62" codeSystem="2.16.840.1.114222.4.5.274"
            displayName="Local Jail"/>
        </playingEntity>
      </participantRole>
    </participant>
    <participant typeCode="DIR">
      <time>
        <low value="20090228"/>
        <high value="20090302"/>
      </time>
      <participantRole classCode="EXPR">
        <scopingEntity>
          <code code="PHC300" codeSystem="2.16.840.1.114222.4.5.274"
            displayName="Household member non-sexual"/>
        </scopingEntity>
      </participantRole>
    </participant>
  </act>
</entry>
```

### 4.3 Acute hepatitis B risk associated procedure

[procedure: templateId 2.16.840.1.113883.10.20.15.3.31]

This clinical statement represents procedures that carry risk for contracting or being exposed to hepatitis B. These may be procedures that are performed in a standard clinical location or may be any location, such as a store, home, or tattoo parlor. The type of location as well as the address of the place where the procedure was performed should be captured. If it is known the procedure was performed, the information should be sent. In some workflows, if the provider explicitly knows that a procedure was NOT done, this information may be sent.

1. **SHALL** contain [1..1] **@classCode**="PROC" *Procedure* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1174)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1175)
3. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3226 Blood or body fluid exposure related procedure **DYNAMIC** (CONF:1176)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1177)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:1178)
6. **SHOULD** contain [0..1] **CCD Location participation** (templateId:2.16.840.1.113883.10.20.1.45) (CONF:1179)



**Figure 26: Acute hepatitis B risk associated procedure example**

```
<entry typeCode="DRIV">
  <!-- Hep B risk associated Procedure-->
  <procedure classCode="PROC" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.31" />
    <code code="428324008" codeSystem="2.16.840.1.113883.6.96"
      displayName="Piercing of tongue" />
    <statusCode code="completed" />
    <effectiveTime value="20081020" />
    <participant typeCode="LOC">
      <templateId root="2.16.840.1.113883.10.20.1.45"/>
      <!-- Location participation template -->
      <participantRole classCode="SDLOC">
        <code code="COMM" codeSystem="2.16.840.1.113883.5.111"
          displayName="Community Location"/>
        <addr>
          <streetAddressLine>1001 Lone Tree Rd</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
        </addr>
        <playingEntity classCode="PLC">
          <name>Mall Store</name>
        </playingEntity>
      </participantRole>
    </participant>
  </procedure>
</entry>
```

## 4.4 Anthrax possible exposure location and type

[act: templateId 2.16.840.1.113883.10.20.15.3.41]

This clinical statement represents locations where it is possible that an exposure to anthrax may have occurred. It can also represent the vomite or fomite that may have transmitted anthrax. These are simply locations or vehicles that have been identified by public health departments as associated with higher risk of coming into contact with anthrax. The reporter is NOT inferring that the patient was definitively exposed in this manner. If known, the likely exposure date or date range should be sent. The possible exposure location should capture the address of the location and it may capture the type of location. The type of location is not restricted to any particular value set.

1. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1447)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1448)
3. **SHALL** contain [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1451), which
  - a. **SHALL** contain [1..1] **qualifier** (CONF:1452) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="246090004" *Associated finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1453)

- ii. **SHALL** contain [1..1] **value/@code**="170475009" *Anthrax exposure* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1454)
- b. **SHALL** contain [1..1] **qualifier** (CONF:1455) (specialized branch), which
  - i. **SHALL** contain [1..1] **name/@code**="408729009" *Finding context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1456)
  - ii. **SHALL** contain [1..1] **value/@code**="410590009" *Known possible* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1457)
- 4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1450)
- 5. **SHALL** contain [1..\*] **participant** (CONF:1458) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1459)
  - b. **SHOULD** contain [0..1] **time** (CONF:1460)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1461), which
    - i. **SHALL** contain [1..1] **@classCode**="LOCE" *Located entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1462)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:1463)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:1464)
    - iv. **MAY** contain [0..1] **playingEntity** (CONF:1465), which if present
      - 1. **SHALL** contain [1..1] **@classCode**="PLC" *Place* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1466)
      - 2. **SHALL** contain [1..1] **code** (CONF:1467)
- 6. **MAY** contain [0..\*] **participant** (CONF:1546) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DIR" *Direct target* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1547)
  - b. **SHOULD** contain [0..1] **time** (CONF:1548)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1549), which
    - i. **SHALL** contain [1..1] **@classCode**="EXPR" *Exposed entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1550)
    - ii. **SHALL** contain [1..1] **scopingEntity** (CONF:1553), which
      - 1. **SHALL** contain [1..1] **@classCode**="ANM" *Animal* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1554)
      - 2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1074 Animal **DYNAMIC** (CONF:1555)
- 7. **MAY** contain [0..\*] **participant** (CONF:1556) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DIR" *Direct target* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1557)
  - b. **SHOULD** contain [0..1] **time** (CONF:1558)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1559), which
    - i. **SHALL** contain [1..1] **@classCode**="EXPR" *Exposed entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1560)
    - ii. **SHALL** contain [1..1] **scopingEntity** (CONF:1561), which
      - 1. **SHALL** contain [1..1] **@classCode**="MAT" *Material* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1562)
      - 2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3211 Material exposure type **DYNAMIC** (CONF:1563)

**Figure 27: Anthrax possible exposure location and type example**

```
<entry typeCode="DRIV">
  <!-- Anthrax Possible exposure location and type-->
  <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.41"/>
    <code code="413350009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Finding with explicit context">
      <qualifier>
        <name code="246090004" displayName="Associated finding"/>
        <value code="170475009" displayName="Anthrax exposure"/>
      </qualifier>
      <qualifier>
        <name code="408729009" displayName="Finding context"/>
        <value code="410590009" displayName="Known possible"/>
      </qualifier>
    </code>
    <statusCode code="completed"/>

    <participant typeCode="LOC">
      <time>
        <low value="20090228"/>
        <high value="20090302"/>
      </time>
      <participantRole classCode="LOCE">
        <addr>
          <streetAddressLine>1001 Lone Tree Rd</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999"/>
        <playingEntity classCode="PLC">
          <code code="257662001" codeSystem="2.16.840.1.113883.6.96"
            displayName="Post office"/>
        </playingEntity>
      </participantRole>
    </participant>
    <participant typeCode="DIR">
      <time>
        <low value="20090228"/>
        <high value="20090302"/>
      </time>
      <participantRole classCode="EXPR">
        <scopingEntity classCode="ANM">
          <code code="125099002" codeSystem="2.16.840.1.113883.6.96"
            displayName="Sheep"/>
        </scopingEntity>
      </participantRole>
    </participant>
    <participant>
      ...
    </participant>
    ...
  </act>
</entry>
```

## 4.5 CCD Encounter activity

[encounter: templateId 2.16.840.1.113883.10.20.1.21]

This clinical statement represents the details of an encounter.

1. The value for “Encounter / @classCode” in an encounter activity SHALL be “ENC” 2.16.840.1.113883.5.6 ActClass STATIC. (CONF: 577).
2. The value for “Encounter / @moodCode” in an encounter activity SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 578).
3. An encounter activity SHALL contain at least one Encounter / id. (CONF: 579).
4. An encounter activity SHOULD contain exactly one Encounter / code. (CONF: 580).
5. The value for “Encounter / code” in an encounter activity SHOULD be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode 2.16.840.1.113883.5.4 ActCode DYNAMIC. (CONF: 581).
6. An encounter activity MAY contain exactly one Encounter / effectiveTime, to indicate date, time, and/or duration of an encounter. (CONF: 582).
7. An encounter activity MAY contain one or more Encounter / entryRelationship, whose value for “entryRelationship / @typeCode” SHALL be “RSON” “Has reason” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, where the target of the relationship represents the indication for the activity. (CONF: 583).
8. An encounter activity MAY contain one or more Encounter / performer, used to define the practioners involved in an encounter. (CONF: 584).
9. Encounter / performer MAY contain exactly one Encounter / performer / assignedEntity / code, to define the role of the practioner. (CONF: 585).
10. An encounter activity MAY contain one or more patient instructions (templateId 2.16.840.1.113883.10.20.1.49). (CONF: 586).
11. The value for “Encounter / entryRelationship / @typeCode” in an encounter activity MAY be “SUBJ” “Subject” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38). (CONF: 587).
12. An encounter activity SHALL contain one or more sources of information, as defined in section 5.2 Source. (CONF: 588).
13. An encounter activity MAY contain one or more location participations (templateId 2.16.840.1.113883.10.20.1.45). (CONF: 589).

## 4.6 CCD Medication activity

[substanceAdministration: templateId 2.16.840.1.113883.10.20.1.24]

A medication activity is used to describe what is administered. Reconciliation of conflicting medication information from various sources is enabled both by the source of information and by indicating whether the source is reporting intended or actual medication use. For instance, a physician may intend for a patient to be on a particular dose, but the patient may actually be taking a different dose; a pharmacy may fill a prescription for a particular dose only to then have the patient's physician lower the dose without notifying the pharmacy. Therefore, medication and supply activities can be expressed in either the "EVN" (event) mood or the "INT" (intent) mood. Medication activities in "INT" mood are not orders, but rather are reflections of what a clinician intends a patient to be taking. Medication activities in "EVN" mood reflect actual use. A pharmacy system will typically report what was actually filled, along with intended use. A physician will often report intended use. A patient or family member will typically report actual use.

1. The value for "SubstanceAdministration / @moodCode" in a medication activity SHALL be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 1013).
2. A medication activity SHALL contain at least one SubstanceAdministration / id. (CONF: 1014).
3. A medication activity SHOULD contain exactly one SubstanceAdministration / statusCode. (CONF: 1015).
4. A medication activity SHOULD contain one or more SubstanceAdministration / effectiveTime elements, used to indicate the actual or intended start and stop date of a medication, and the frequency of administration. (See section 5.4.1 Dates and Times for additional details about time representation). (CONF: 1016).
5. A medication activity SHOULD contain exactly one SubstanceAdministration / routeCode. (CONF: 1017).
6. The value for "SubstanceAdministration / routeCode" in a medication activity SHOULD be selected from the HL7 RouteOfAdministration (2.16.840.1.113883.5.112) code system. (CONF: 1018).
7. A medication activity SHOULD contain exactly one SubstanceAdministration / doseQuantity or SubstanceAdministration / rateQuantity. (CONF: 1019).
8. A medication activity MAY contain exactly one SubstanceAdministration / maxDoseQuantity, which represents a maximum dose limit. (CONF: 1020).
9. A medication activity MAY contain one or more SubstanceAdministration / performer, to indicate the person administering a substance. (CONF: 1021).
10. A medication activity MAY have one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF: 1022).
11. A medication activity SHALL contain one or more sources of information, as defined in section 5.2 Source. (CONF: 1023).
12. A medication activity MAY contain exactly one medication status observation. (CONF: 1024).
13. A medication activity SHALL contain exactly one SubstanceAdministration / consumable, the target of which is a product template (CONF: 1051).
14. A medication activity MAY contain exactly one medication series number observations (CONF: 2019).

#### 4.6.1 Acute hepatitis B immunization activity

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.25]

This clinical statement represents details about the immunization administration for hepatitis B. This template constrains the CCD template by specifying the hepatitis B immunizations that should be recorded.

1. Conforms to CCD Medication activity Template (templateId: 2.16.840.1.113883.10.20.1.24).
2. **SHALL** contain [1..1] **consumable** (CONF:1052), which
  - a. **SHALL** contain [1..1] **Acute hepatitis B immunization product** (templateId:2.16.840.1.113883.10.20.15.3.24) (CONF:1053)

**Figure 28: Acute hepatitis B immunization activity example**

```
<entry typeCode="DRIV">
  <!-- Acute Hepatitis B immunization activity -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.25" />
    <!-- CCD Medication activity template -->
    <id root="e6f1ba43-c0ed-4b9b-9f12-f435d8ad8f92" />
    <statusCode code="completed" />
    <effectiveTime xsi:type="IVL_TS">
      <center value="200004" />
      <!--date of hep B dose -->
    </effectiveTime>
    <routeCode code="IM" codeSystem="2.16.840.1.113883.5.112"
      codeSystemName="RouteOfAdministration"
      displayName="Intramuscular injection" />
    <consumable>
      <manufacturedProduct>
        <templateId root="2.16.840.1.113883.10.20.15.3.24" />
        <manufacturedMaterial>
          <code code="43" codeSystem="2.16.840.1.113883.6.59"
            displayName="Hep B, adult">
            <originalText>hepatitis B vaccine, adult dosage</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
    <entryRelationship typeCode="SUBJ">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.46" />
        <!-- CCD medication series number template -->
        <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
          displayName="Dose number" />
        <!-- Dose Number -->
        <statusCode code="completed" />
        <value xsi:type="INT" value="1" />
      </observation>
    </entryRelationship>
  </substanceAdministration>
</entry>
```

## 4.7 CCD Medication series number observation

[observation: templateId 2.16.840.1.113883.10.20.1.46]

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g., “hepatitis B vaccine number 2 was administered on Feb 07, 2004”).

1. The value for “entryRelationship / @typeCode” in a relationship between a medication activity and medication series number observation SHALL be “SUBJ” “Subject” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF: 1029).
2. A medication series number observation (templateId 2.16.840.1.113883.10.20.1.46) SHALL be represented with Observation. (CONF: 1030).
3. The value for “Observation / @classCode” in a medication series number observation SHALL be “OBS” 2.16.840.1.113883.5.6 ActClass STATIC. (CONF: 1031).
4. The value for “Observation / @moodCode” in a medication series number observation SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 1032).
5. A medication series number observation SHALL include exactly one Observation / statusCode. (CONF: 1033).
6. A medication series number observation SHALL contain exactly one Observation / code. (CONF: 1034).
7. The value for “Observation / code” in a medication series number observation SHALL be “30973-2” “Dose number” 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 1035).
8. A medication series number observation SHALL contain exactly one Observation / value. (CONF: 1036).
9. The data type for “Observation / value” in a medication series number observation SHALL be INT (integer). (CONF: 1037).

## 4.8 CCD Problem observation

[observation: templateId 2.16.840.1.113883.10.20.1.28]

This clinical statement represents the details of a patient’s problem or diagnosis.

1. The value for “Observation / @moodCode” in a problem observation SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
3. The value for “Observation / statusCode” in a problem observation SHALL be “completed” 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
4. A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).
5. The value for “Observation / code” in a problem observation MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017. (CONF: 818).
6. The value for “Observation / entryRelationship / @typeCode” in a problem observation MAY be “SUBJ” “Subject” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38). (CONF: 819).
7. A problem observation SHALL contain one or more sources of information, as defined in section 5.2 Source. (CONF: 820).

#### 4.8.1 PHCR Case observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.54]

This clinical statement represents the case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. All known symptom observations should be sent. In some workflows, it should be asserted if it is known the patient did NOT have a typical symptom. This template contains 4 of the 5 data elements determined by the CRSWg to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. Conforms to CCD Problem observation Template (templateId: 2.16.840.1.113883.10.20.1.28).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1868)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1869)
4. **MAY** contain [0..\*] **id** (CONF:1870)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1871)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1872)
7. **SHOULD** contain [0..1] **effectiveTime/low** (CONF:1873)
8. **SHALL** contain [1..1] **value/@code** (CONF:1874)
9. **SHOULD** contain [0..1] **author** (CONF:1875), which if present
  - a. **SHALL** contain [1..1] **time** (CONF:1876)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:1877), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1878)
    - ii. **MAY** contain [0..\*] **addr** (CONF:1879)
    - iii. **MAY** contain [0..\*] **telecom** (CONF:1880)
    - iv. **MAY** contain [0..1] **assignedPerson** (CONF:1881), which if present
      1. **MAY** contain [0..1] **name** (CONF:1882)
    - v. **MAY** contain [0..1] **representedOrganization** (CONF:1883)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:1884) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1885)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:1886)
11. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1887) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="MFST" *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1888)
  - b. **SHALL** contain [1..1] **@inversionInd**="true" (CONF:1889)



- c. **SHALL** contain [1..1] **PHCR signs and symptoms**  
(templateId:2.16.840.1.113883.10.20.15.3.53) (CONF:1890)

#### 4.8.1.1 Acute hepatitis B case observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.30]

This clinical statement represents the acute hepatitis B case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis of acute hepatitis B, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. This template contains 4 of the 5 data elements determined by the CRSWg to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. Conforms to PHCR case observation Template (templateId: 2.16.840.1.113883.10.20.15.3.54).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1146)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1147)
4. **MAY** contain [0..\*] **id** (CONF:1148)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1149)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1150)
7. **SHOULD** contain [0..1] **effectiveTime/low** (CONF:1151)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3221 Disease Type (Acute Hepatitis B) **DYNAMIC** (CONF:1152)
9. **SHOULD** contain [0..1] **author** (CONF:1154), which if present
  - a. **SHALL** contain [1..1] **time** (CONF:1155)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:1156), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1157)
    - ii. **MAY** contain [0..\*] **addr** (CONF:1158)
    - iii. **MAY** contain [0..\*] **telecom** (CONF:1159)
    - iv. **MAY** contain [0..1] **assignedPerson** (CONF:1160), which if present
      1. **MAY** contain [0..1] **name** (CONF:1161)
    - v. **MAY** contain [0..1] **representedOrganization** (CONF:1162)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:1163) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1164)
  - b. **SHALL** contain [1..1] **CCD Problem status observation**  
(templateId:2.16.840.1.113883.10.20.1.50) (CONF:1165)
11. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1170) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="MFST" *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1171)

- b. **SHALL** contain [1..1] **@inversionInd="true"** (CONF:1172)
- c. **SHALL** contain [1..1] **Acute hepatitis B signs and symptoms**  
(templateId:2.16.840.1.113883.10.20.15.3.22) (CONF:1173)

**Figure 29: Acute hepatitis B case observation example**

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <!-- Acute Hep B case observation -->
    <templateId root="2.16.840.1.113883.10.20.15.3.30" />
    <id root="d11275e7-67ae-11db-bd13-0800200c9a66" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20081230" />
    </effectiveTime>
    <value xsi:type="CD" code="76795007" codeSystem="2.16.840.1.113883.6.96"
      displayName="Acute hepatitis B" />
    <author>
      <time value="20090107" />
      <assignedAuthor>
        <id nullFlavor="NI" />
        <addr>
          <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Patricia</given>
            <family>Primary</family>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="2.16.840.1.113883.19.5" />
          <name>Good Health Hospital</name>
        </representedOrganization>
      </assignedAuthor>
    </author>
    <entryRelationship>
      ...
    </entryRelationship>
    ...
  </observation>
</entry>
```

#### 4.8.1.2 Anthrax case observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.36]

This clinical statement represents the anthrax case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis of anthrax, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. All anthrax known symptom observations should be sent. In some workflows, it should be asserted if it is known the patient did NOT have a typical anthrax symptom. This template contains 4 of the 5 data elements determined by the CRSWg to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. Conforms to PHCR case observation Template (templateId: 2.16.840.1.113883.10.20.15.3.54).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1297)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1298)
4. **MAY** contain [0..\*] **id** (CONF:1299)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1300)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1301)
7. **SHOULD** contain [0..1] **effectiveTime/low** (CONF:1302)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3220 Disease Type (Anthrax) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:1303)
9. **SHOULD** contain [0..1] **author** (CONF:1304), which if present
  - a. **SHALL** contain [1..1] **time** (CONF:1305)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:1306), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1307)
    - ii. **MAY** contain [0..\*] **addr** (CONF:1308)
    - iii. **MAY** contain [0..\*] **telecom** (CONF:1309)
    - iv. **MAY** contain [0..1] **assignedPerson** (CONF:1310), which if present
      1. **MAY** contain [0..1] **name** (CONF:1311)
    - v. **MAY** contain [0..1] **representedOrganization** (CONF:1312)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:1313) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1314)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:1315)
11. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1320) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="MFST" *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1321)
  - b. **SHALL** contain [1..1] **@inversionInd**="true" (CONF:1322)

- c. **SHALL** contain [1..1] **Anthrax signs and symptoms**  
(templateId:2.16.840.1.113883.10.20.15.3.35) (CONF:1323)

**Figure 30: Anthrax case observation example**

```
<entry typeCode="DRIV">
  <!-- Anthrax case observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.36"/>
    <id root="d9f34320-0814-11de-8c30-0800200c9a66"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="200890310"/>
    </effectiveTime>
    <value xsi:type="CD" code="84980006" codeSystem="2.16.840.1.113883.6.96"
      displayName="Cutaneous anthrax"/>
    <author>
      <time value="20090107"/>
      <assignedAuthor>
        <id nullFlavor="NI"/>
        <addr>
          <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999"/>
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Patricia</given>
            <family>Primary</family>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="2.16.840.1.113883.19.5"/>
          <name>Good Health Clinic</name>
        </representedOrganization>
      </assignedAuthor>
    </author>
    <entryRelationship typeCode="REFR">
      ...
    </entryRelationship>
    ...
  </observation>
</entry>
```

#### 4.8.1.3 Tuberculosis case observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.11]

This clinical statement represents the tuberculosis case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis of tuberculosis, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. In some workflows, it should be asserted if it is known the patient did NOT have a typical tuberculosis symptom. This template contains 4 of the 5 data elements determined by the CRSWg to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. Conforms to PHCR case observation Template (templateId: 2.16.840.1.113883.10.20.15.3.54).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:333)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:334)
4. **MAY** contain [0..\*] **id** (CONF:340)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:336)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:337)
7. **SHOULD** contain [0..1] **effectiveTime/low** (CONF:338)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3222 Disease Type (TB) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:339)
9. **SHOULD** contain [0..\*] **targetSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:341)
10. **SHOULD** contain [0..1] **author** (CONF:342), which if present
  - a. **SHALL** contain [1..1] **time** (CONF:359)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:361), which
    - i. **SHALL** contain [1..\*] **id** (CONF:362)
    - ii. **MAY** contain [0..\*] **addr** (CONF:363)
    - iii. **MAY** contain [0..\*] **telecom** (CONF:365)
    - iv. **MAY** contain [0..1] **assignedPerson** (CONF:366), which if present
      1. **MAY** contain [0..1] **name** (CONF:367)
    - v. **MAY** contain [0..1] **representedOrganization** (CONF:368)
11. **SHOULD** contain [0..1] **entryRelationship** (CONF:512) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:513)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:515)
12. **SHOULD** contain [0..\*] **entryRelationship** (CONF:350) (specialized branch), which if present

- a. **SHALL** contain [1..1] **@typeCode="MFST"** *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:347)
- b. **SHALL** contain [1..1] **@inversionInd="true"** (CONF:348)
- c. **SHALL** contain [1..1] **Tuberculosis signs and symptoms** (templateId:2.16.840.1.113883.10.20.15.3.14) (CONF:349)

**Figure 31 Tuberculosis case observation example**

```
<entry typeCode="DRIV">
  <!-- TB case observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.11"/>
    <id root="d11275e7-67ae-11db-bd13-0800200c9a66" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20081230" />
    </effectiveTime>
    <value xsi:type="CD" code="56717001" codeSystem="2.16.840.1.113883.6.96"
      displayName="Tuberculosis" />
    <!-- Body Site -->
    <targetSiteCode code="39607008" codeSystem="2.16.840.1.113883.6.96"
      displayName="Lung structure"/>
    <author>
      <time value="20090107" />
      <assignedAuthor>
        <id nullFlavor="NI" />
        <addr>
          <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Patricia</given>
            <family>Primary</family>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="2.16.840.1.113883.19.5" />
          <name>Good Health Hospital</name>
        </representedOrganization>
      </assignedAuthor>
    </author>
    <entryRelationship>
      ...
    </entryRelationship>
    ...
  </observation>
</entry>
```

#### 4.8.1.4 Tularemia case observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.46]

This clinical statement represents the tularemia case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis of tularemia, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. All tularemia known symptom observations should be sent. In some workflows, it should be asserted if it is known the patient did NOT have a typical tularemia symptom. In addition, the location of the tularemia lesion may be represented. This template contains 4 of the 5 data elements determined by the CSTE/NCPHI project to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. Conforms to PHCR case observation Template (templateId: 2.16.840.1.113883.10.20.15.3.54).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1687)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1688)
4. **MAY** contain [0..\*] **id** (CONF:1689)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1690)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1691)
7. **SHOULD** contain [0..1] **effectiveTime/low** (CONF:1692)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3223 Disease Type (Tularemia) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:1693)
9. **SHOULD** contain [0..1] **author** (CONF:1694), which if present
  - a. **SHALL** contain [1..1] **time** (CONF:1695)
  - b. **SHALL** contain [1..1] **assignedAuthor** (CONF:1696), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1697)
    - ii. **MAY** contain [0..\*] **addr** (CONF:1698)
    - iii. **MAY** contain [0..\*] **telecom** (CONF:1699)
    - iv. **MAY** contain [0..1] **assignedPerson** (CONF:1700), which if present
      1. **MAY** contain [0..1] **name** (CONF:1701)
    - v. **MAY** contain [0..1] **representedOrganization** (CONF:1702)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:1703) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1704)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:1705)
11. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1706) (specialized branch), which if present

- a. **SHALL** contain [1..1] **@typeCode="MFST"** *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1707)
  - b. **SHALL** contain [1..1] **@inversionInd="true"** (CONF:1708)
  - c. **SHALL** contain [1..1] **Tularemia signs and symptoms** (templateId:2.16.840.1.113883.10.20.15.3.45) (CONF:1709)
12. **MAY** contain [0..\*] **entryRelationship** (CONF:1710) (specialized branch), which if present
- a. **SHALL** contain [1..1] **@typeCode="MFST"** *Is manifestation of* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1711)
  - b. **SHALL** contain [1..1] **@inversionInd="true"** (CONF:1712)
  - c. **SHALL** contain [1..1] **Location of lesion observation** (templateId:2.16.840.1.113883.10.20.15.3.44) (CONF:1713)



**Figure 32 Tularemia case observation example**

```
<entry typeCode="DRIV">
  <!-- Tularemia case observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.46"/>
    <id root="d9f34320-0814-11de-8c30-0800200c9a66" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="200890310" />
    </effectiveTime>
    <value xsi:type="CD" code="398554008" codeSystem="2.16.840.1.113883.6.96"
      displayName="Typhoidal tularemia" />
    <author>
      <time value="20090510" />
      <assignedAuthor>
        <id nullFlavor="NI" />
        <addr>
          <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Patricia</given>
            <family>Primary</family>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="2.16.840.1.113883.19.5" />
          <name>Good Health Hospital</name>
        </representedOrganization>
      </assignedAuthor>
    </author>

    <entryRelationship>
      <observation>
        ...
      </observation>
    </entryRelationship>
    ...
  </observation>
</entry>
```

## 4.8.2 Imaging observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.5]

This clinical statement represents radiologic image findings. It may be a simple coded value of an overall impression of a study, such as "radiologic infiltrates" and a statement of the procedure method that was used, such as "standard chest x-ray". Or, it could be an assertion of a finding with a narrative text explanation similar to the "Impression" section of a radiology report. It may also reference an external diagnostic image or the entire external document radiology report. The code/value can be coded (e.g., assertion: nodule) or it can be largely narrative (e.g., finding: A complete white out of left lung seen. The chest tube is dislodged.).

1. Conforms to CCD Problem observation Template (templateId: 2.16.840.1.113883.10.20.1.28).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:829)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:830)
4. **SHALL** contain [1..1] **templateId/@root**="2.16.840.1.113883.10.20.15.3.5" (CONF:849)
5. **SHALL** contain [1..\*] **id** (CONF:821)
6. **SHALL** contain [1..1] **code** (CONF:822)
7. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:823)
8. **SHOULD** contain [0..1] **effectiveTime** (CONF:824)
9. **SHALL** contain [1..1] **value** (CONF:825)
10. **MAY** contain [0..1] **methodCode** (CONF:826)
11. **MAY** contain [0..\*] **reference** (CONF:827), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:828)
  - b. **SHALL** contain [1..1] **externalObservation** (CONF:831), which
    - i. **SHALL** contain [1..1] **@classCode**="DGIMG" *Diagnostic image* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:832)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:833)
    - iii. **SHALL** contain [1..1] **id** (CONF:834)
    - iv. **SHALL** contain [1..1] **code** (CONF:835)
12. **MAY** contain [0..1] **reference** (CONF:842), which if present
  - a. **SHALL** contain **@typeCode** (CONF:843)
  - b. **SHALL** contain [1..1] **externalDocument** (CONF:844), which
    - i. **SHALL** contain [1..1] **@classCode**="DOCCLIN" *Clinical document* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:845)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:846)
    - iii. **SHALL** contain [1..1] **id** (CONF:847)
    - iv. **SHALL** contain [1..1] **code** (CONF:848)

**Figure 33: Imaging observation example**

```
<entry typeCode="DRIV">
  <!-- Imaging observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.5"/>
    <id nullFlavor="NI"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed" />
    <effectiveTime value="20090107"/> <!-- Date of X-ray -->
    <value xsi:type="CD" code="128309002" codeSystem="2.16.840.1.113883.6.96"
      displayName="Radiologic infiltrate" />
    <methodCode code="168731009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Standard chest X-ray"/>

    <reference typeCode="SUBJ">
      <externalObservation classCode="DGIMG" moodCode="EVN">
        <id root="6757bb69-81dc-4268-897a-2e06f4b1806d"/>
        <code code="168731009" codeSystem="2.16.840.1.113883.6.96"
          displayName="Standard chest X-ray" /> <!-- X-ray name -->
        </externalObservation>
      </reference>

    <reference typeCode="XCRPT">
      <externalDocument classCode="DOCCLIN" moodCode="EVN">
        <id root="1.2.840.113619.2.62.994044785528.12"
          extension="20060828170821659"/>
        <code code="18782-3" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="X-Ray Report"/>
        </externalDocument>
      </reference>

    </observation>
  </entry>
```

### 4.8.3 STD history observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.33]

This clinical statement represents the patient's history of sexually transmitted disease diagnoses and treatment. This template is a simple problem observation template modeled after CCD problem observation and problem status templates to show the history of STDs with an additional act to show if the STD was treated or not.

1. Conforms to CCD Problem observation Template (templateId: 2.16.840.1.113883.10.20.1.28).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1199)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1200)
4. **MAY** contain [0..\*] **id** (CONF:1201)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1202)

6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1203)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1204)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3231 Disease Type (STD) **DYNAMIC** (CONF:1205)
9. **SHOULD** contain [0..1] **entryRelationship** (CONF:1206) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1207)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:1208)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:1209) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1210)
  - b. **SHALL** contain [1..1] **act** (CONF:1217), which
    - i. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1211)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1212)
    - iii. **SHALL** contain **@negationInd** (CONF:1213)
    - iv. **SHALL** contain [1..1] **code/@code**="133877004" *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1214)
    - v. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1215)
    - vi. **SHOULD** contain [0..1] **effectiveTime** (CONF:1216)

**Figure 34: STD history observation example**

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.33" />
    <!-- STD history observation -->
    <id root="NI" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="2004" />
      <high value="2004" />
    </effectiveTime>
    <value xsi:type="CD" code="8098009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Sexually transmitted disease" />
    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.50" />
        <!-- Problem status observation template -->
        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Status" />
        <statusCode code="completed" />
        <value xsi:type="CE" code="413322009" codeSystem="2.16.840.1.113883.6.96"
          displayName="Resolved" />
      </observation>
    </entryRelationship>
    <entryRelationship typeCode="REFR">
      <act classCode="ACT" moodCode="EVN" negationInd="false">
        <code code="133877004" codeSystem="2.16.840.1.113883.6.96"
          displayName="Therapeutic regimen" />
        <statusCode code="completed" />
        <effectiveTime value="2004"/>
      </act>
    </entryRelationship>
  </observation>
</entry>
```

#### 4.8.4 Viral hepatitis history observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.32]

This clinical statement represents the history of cases of viral hepatitis that the subject of the case report has been diagnosed with other than the one being reported. This template is a simple problem observation template modeled after CCD problem observation and problem status templates to show the history of other viral hepatitis problems.

1. Conforms to CCD Problem observation Template (templateId: 2.16.840.1.113883.10.20.1.28).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1189)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1190)
4. **MAY** contain [0..\*] **id** (CONF:1191)

5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1192)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1193)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1194)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3230 Disease Type (Hepatitis) **DYNAMIC** (CONF:1195)
9. **SHOULD** contain [0..1] **entryRelationship** (CONF:1196) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1197)
  - b. **SHALL** contain [1..1] **CCD Problem status observation** (templateId:2.16.840.1.113883.10.20.1.50) (CONF:1198)

**Figure 35: Viral hepatitis history observation example**

```
<entry typeCode="DRIV">
  <!-- Viral hepatitis history observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.32" />
    <id root="NI" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20050610" />
      <high value="20050815" />
    </effectiveTime>
    <value xsi:type="CD" code="40468003" codeSystem="2.16.840.1.113883.6.96"
      displayName="Hepatitis A" />
    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.50" />
        <!-- Problem status observation template -->
        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Status" />
        <statusCode code="completed" />
        <value xsi:type="CE" code="413322009" codeSystem="2.16.840.1.113883.6.96"
          displayName="Resolved" />
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

## 4.9 CCD Result observation

[observation: templateId 2.16.840.1.113883.10.20.1.31]

This clinical statement represents details of a lab, radiology, or other study performed on a patient.

1. The value for "Observation / @moodCode" in a result observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 800).

2. A result observation SHALL contain at least one Observation / id. (CONF: 801).
3. A result observation SHALL contain exactly one Observation / statusCode. (CONF: 802).
4. A result observation SHOULD contain exactly one Observation / effectiveTime, which represents the biologically relevant time (e.g. time the specimen was obtained from the patient). (CONF: 803).
5. A result observation SHALL contain exactly one Observation / code. (CONF: 804).
6. The value for "Observation / code" in a result observation SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF: 805).
7. A result observation MAY contain exactly one Observation / methodCode if the method isn't inherent in Observation / code or if there is a need to further specialize the method in Observation / code. (CONF: 806).
8. Observation / methodCode SHALL NOT conflict with the method inherent in Observation / code. (CONF: 807).
9. A result observation SHALL contain exactly one Observation / value. (CONF: 808).
10. Where Observation / value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF: 809).
11. A result observation SHOULD contain exactly one Observation / interpretationCode, which can be used to provide a rough qualitative interpretation of the observation, such as "N" (normal), "L" (low), "S" (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation. (CONF: 810).
12. A result observation SHOULD contain one or more Observation / referenceRange to show the normal range of values for the observation result. (CONF: 811).

#### 4.9.1 PHCR Result observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.58]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. In addition, it captures the name of organization where the specimen was collected. Note: Where there is a specimen, one can set the specimenRole/id to equal the specimen collection procedure's participantRole[@classCode="SPEC"]/id in order to assert that this observation is being made on the specimen collected in the corresponding specimen collection procedure.

1. Conforms to CCD Result observation Template (templateId: 2.16.840.1.113883.10.20.1.31).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1967)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1968)
4. **SHALL** contain [1..\*] **id** (CONF:1969)
5. **SHALL** contain [1..1] **code** (CONF:1970)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1971)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1972)
8. **SHALL** contain [1..1] **value** (CONF:1973)

9. **MAY** contain [0..1] **specimen** (CONF:1974), which if present
  - a. **SHALL** contain [1..1] **specimenRole** (CONF:1975), which
    - i. **SHOULD** contain [0..1] **id** (CONF:1976)
    - ii. **MAY** contain [0..1] **specimenPlayingEntity** (CONF:1977), which if present
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1978)
10. **SHOULD** contain [0..1] **performer** (CONF:1979), which if present
  - a. **SHOULD** contain [0..1] **time** (CONF:1980)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1981), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1982)
11. **MAY** contain [0..1] **participant** (CONF:1983) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1984)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:1985), which
    - i. **SHALL** contain [1..1] **@classCode**="ISLT" *Isolate* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1986)
    - ii. **SHOULD** contain [0..\*] **id** (CONF:1987)
    - iii. **SHOULD** contain [0..1] **playingEntity** (CONF:1988), which if present
      1. **SHOULD** contain [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1009 Microorganism **DYNAMIC** (CONF:1989)
12. **MAY** contain [0..\*] **entryRelationship** (CONF:1990) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1991)
  - b. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1992)
13. **MAY** contain [0..\*] **entryRelationship** (CONF:1993) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1994)
  - b. **SHALL** contain [1..1] **Susceptibility result** (templateId:2.16.840.1.113883.10.20.15.3.10) (CONF:1995)

#### 4.9.1.1 Acute hepatitis B result observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.34]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. In addition, it captures the name of organization where the specimen was collected.

1. Conforms to PHCR Result observation Template (templateId: 2.16.840.1.113883.10.20.15.3.58).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1233)



3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1234)
4. **SHALL** contain [1..\*] **id** (CONF:1235)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3206 Lab Test Result Name (Acute Hepatitis B) **DYNAMIC** (CONF:1236)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1237)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1238)
8. **SHALL** contain [1..1] **value** (CONF:1239)
9. **SHOULD** contain [0..\*] **interpretationCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC** (CONF:1240)
10. **SHOULD** contain [0..\*] **referenceRange** (CONF:1241), which if present
  - a. **SHALL** contain [1..\*] **observationRange** (CONF:1242)
11. **MAY** contain [0..1] **specimen** (CONF:1246), which if present
  - a. **SHALL** contain [1..1] **specimenRole** (CONF:1247), which
    - i. **SHOULD** contain [0..1] **id** (CONF:1248)
    - ii. **MAY** contain [0..1] **specimenPlayingEntity** (CONF:1249), which if present
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1250)
12. **SHOULD** contain [0..1] **performer** (CONF:1251), which if present
  - a. **SHOULD** contain [0..1] **time** (CONF:1252)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1253), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1254)
13. **MAY** contain [0..\*] **entryRelationship** (CONF:1255) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1256)
  - b. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1257)

**Figure 36: Acute hepatitis B result observation example**

```
<entry typeCode="DRIV">
<!-- Hep B Result observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.34" />
    <id nullFlavor="NI"/>
    <code code="31204-1" codeSystem="2.16.840.1.113883.6.1"
      displayName="Hepatitis B virus core Ab.IgM" />
    <statusCode code="completed" />
    <effectiveTime value="20090304" />
    <value xsi:type="CD" code="10828004" codeSystem="2.16.840.1.113883.6.96"
      displayName="Positive" />
  </observation>
</entry>
<entry typeCode="DRIV">
<!-- Lab observation with ref range and interpretation code-->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.34" />
    <id nullFlavor="NI"/>
    <code code="1920-8" codeSystem="2.16.840.1.113883.6.1"
      displayName="Aspartate aminotransferase" />
    <statusCode code="completed" />
    <effectiveTime value="20090104" />
    <value xsi:type="PQ" value="50" unit="U/L" />
    <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83" />
    <referenceRange>
      <observationRange>
        <!-- referenceRange-->
        <value xsi:type="IVL_PQ">
          <low value="5" unit="U/L" />
          <high value="40" unit="U/L" />
        </value>
      </observationRange>
    </referenceRange>
  </observation>
</entry>
```

#### 4.9.1.2 Anthrax result observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.39]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. If applicable, it may capture the physical body location from where the specimen for the lab report was taken from the subject. In addition, it captures the name of the organization where the specimen was collected. This anthrax result observation also contains a susceptibility clinical statement.

1. Conforms to PHCR Result observation Template (templateId: 2.16.840.1.113883.10.20.15.3.58).
2. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1373)

3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1374)
4. **SHALL** contain [1..\*] **id** (CONF:1375)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3207 Lab Test Result Name (Anthrax) **DYNAMIC** (CONF:1376)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1377)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1378)
8. **SHALL** contain [1..1] **value** (CONF:1379)
9. **MAY** contain [0..1] **specimen** (CONF:1402), which if present
  - a. **SHALL** contain [1..1] **specimenRole** (CONF:1403), which
    - i. **SHOULD** contain [0..1] **id** (CONF:1404), which if present
      1. **MAY** contain [0..1] **specimenPlayingEntity** (CONF:1405), which if present
        - a. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1406)
10. **SHOULD** contain [0..1] **performer** (CONF:1407), which if present
  - a. **SHOULD** contain [0..1] **time** (CONF:1408)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1409), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1410)
11. **MAY** contain [0..1] **participant** (CONF:1411) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1412)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:1413), which
    - i. **SHALL** contain [1..1] **@classCode**="ISLT" *Isolate* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1414)
    - ii. **SHOULD** contain [0..\*] **id** (CONF:1415)
    - iii. **SHOULD** contain [0..1] **playingEntity** (CONF:1416), which if present
      1. **SHOULD** contain [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1009 Microorganism **DYNAMIC** (CONF:1417)
12. **MAY** contain [0..\*] **entryRelationship** (CONF:1418) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1419)
  - b. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1420)
13. **MAY** contain [0..\*] **entryRelationship** (CONF:1421) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1422)
  - b. **SHALL** contain [1..1] **Susceptibility result** (templateId:2.16.840.1.113883.10.20.15.3.10) (CONF:1423)

**Figure 37: Anthrax result observation example**

```
<component>
  <!-- Anthrax Result Observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.39"/>
    <code code="17915-0" codeSystem="2.16.840.1.113883.6.1"
      displayName="Bacteria identified - Wound.shlw - Aerobic culture "/>
    <!-- Test name -->
    <statusCode code="completed"/>
    <effectiveTime value="20081215"/>
    <!-- Specimen collection date-->
    <value xsi:type="CD" code="21927003" codeSystem="2.16.840.1.113883.6.96"
      displayName="Bacillus anthracis"/>
    <!-- Test result -->
    <performer>
      <time value="20090309"/>
      <!-- Date of test on specimen -->
      <assignedEntity>
        <id nullFlavor="NI"/>
      </assignedEntity>
    </performer>
    <participant typeCode="SBJ">
      <participantRole classCode="ISLT">
        <id root="63af5c4e-2b78-4d41-bd38-9c3caaf86d64"/>
        <playingEntity>
          <code code="21927003" codeSystem="2.16.840.1.113883.6.96"
            displayName="Bacillus anthracis"/>
        </playingEntity>
      </participantRole>
    </participant>
    <entryRelationship typeCode="COMP">
      ...
    </entryRelationship>
    ...
  </observation>
</component>
```

#### 4.9.1.3 Tuberculosis result observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.13]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. If applicable, it may capture the physical body location from where the specimen for the lab report was taken from the subject. In addition, it captures the name of organization where the specimen was collected. This tuberculosis result observation also contains a susceptibility clinical statement.

1. Conforms to PHCR Result observation Template (templateId: 2.16.840.1.113883.10.20.15.3.58).
2. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:717)

3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:718)
4. **SHALL** contain [1..\*] **id** (CONF:813)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) **DYNAMIC** (CONF:719)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:720)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:721)
8. **SHALL** contain [1..1] **value** (CONF:722)
9. **MAY** contain [0..1] **specimen** (CONF:723), which if present
  - a. **SHALL** contain [1..1] **specimenRole** (CONF:724), which
    - i. **SHOULD** contain [0..1] **id** (CONF:725)
    - ii. **MAY** contain [0..1] **specimenPlayingEntity** (CONF:726), which if present
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:727)
10. **SHOULD** contain [0..1] **performer** (CONF:728), which if present
  - a. **SHOULD** contain [0..1] **time** (CONF:729)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:730), which
    - i. **SHALL** contain [1..\*] **id** (CONF:731)
11. **MAY** contain [0..1] **participant** (CONF:790) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:791)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:792), which
    - i. **SHALL** contain [1..1] **@classCode**="ISLT" *Isolate* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:793)
    - ii. **SHOULD** contain [0..\*] **id** (CONF:794)
    - iii. **SHOULD** contain [0..1] **playingEntity** (CONF:795), which if present
      1. **SHOULD** contain [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1009 Microorganism **DYNAMIC** (CONF:796)
12. **MAY** contain [0..\*] **entryRelationship** (CONF:732) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:733)
  - b. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:734)
13. **MAY** contain [0..\*] **entryRelationship** (CONF:797) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:798)
  - b. **SHALL** contain [1..1] **Susceptibility result** (templateId:2.16.840.1.113883.10.20.15.3.10) (CONF:799)

**Figure 38: Tuberculosis result observation example**

```
<component>
<!-- TB Result Observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.13"/>
    <id nullFlavor="NI"/>
    <code code="539-7" codeSystem="2.16.840.1.113883.6.1"
      displayName="Mycobacterium species identified" />
    <!-- Test name -->
    <statusCode code="completed" />
    <effectiveTime value="20081215"/> <!-- Specimen collection date-->
    <value xsi:type="CD" code="113861009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Mycobacterium tuberculosis"/> <!-- Test result -->
    <performer>
      <time value="20081215"/> <!-- Date of test on specimen -->
      <assignedEntity>
        <id nullFlavor="NI"/>
      </assignedEntity>
    </performer>
    <participant typeCode="SBJ">
      <participantRole classCode="ISLT">
        <id root="63af5c4e-2b78-4d41-bd38-9c3caaf86d64"/>
        <playingEntity>
          <code code="113861009" codeSystem="2.16.840.1.113883.6.96"
            displayName="Mycobacterium tuberculosis"/>
        </playingEntity>
      </participantRole>
    </participant>
  </observation>
</component>
```

#### 4.9.1.4 Tularemia result observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.51]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. If applicable, it may capture the physical body location from where the specimen for the lab report was taken from the subject. In addition, it captures the name of organization where the specimen was collected. This tularemia result observation also contains a susceptibility clinical statement.

1. Conforms to PHCR Result observation Template (templateId: 2.16.840.1.113883.10.20.15.3.58).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1785)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1786)
4. **SHALL** contain [1..\*] **id** (CONF:1787)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3208 Lab Test Result Name (Tularemia) **DYNAMIC** (CONF:1788)

6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1789)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1790)
8. **SHALL** contain [1..1] **value** (CONF:1791)
9. **MAY** contain [0..1] **specimen** (CONF:1792), which if present
  - a. **SHALL** contain [1..1] **specimenRole** (CONF:1793), which
    - i. **SHOULD** contain [0..1] **id** (CONF:1794)
    - ii. **MAY** contain [0..1] **specimenPlayingEntity** (CONF:1795), which if present
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1796)
10. **SHOULD** contain [0..1] **performer** (CONF:1797), which if present
  - a. **SHOULD** contain [0..1] **time** (CONF:1798)
  - b. **SHALL** contain [1..1] **assignedEntity** (CONF:1799), which
    - i. **SHALL** contain [1..\*] **id** (CONF:1800)
11. **MAY** contain [0..1] **participant** (CONF:1801) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1802)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:1803), which
    - i. **SHALL** contain [1..1] **@classCode**="ISLT" *Isolate* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1804)
    - ii. **SHOULD** contain [0..\*] **id** (CONF:1805)
    - iii. **SHOULD** contain [0..1] **playingEntity** (CONF:1806), which if present
      1. **SHOULD** contain [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1009 Microorganism **DYNAMIC** (CONF:1807)
12. **MAY** contain [0..\*] **entryRelationship** (CONF:1808) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1809)
  - b. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1810)
13. **MAY** contain [0..\*] **entryRelationship** (CONF:1811) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1812)
  - b. **SHALL** contain [1..1] **Susceptibility result** (templateId:2.16.840.1.113883.10.20.15.3.10) (CONF:1813)

**Figure 39: Tularemia result observation example**

```
<component>
  <!-- Tularemia Result Observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.51"/>
    <id nullFlavor="NI"/>
    <code code="600-7" codeSystem="2.16.840.1.113883.6.1"
      displayName="Bacteria identified - Bld" /> <!-- Test name -->
    <statusCode code="completed" />
    <effectiveTime value="20090508"/> <!-- Specimen collection date-->
    <value xsi:type="CD" code="51526001" codeSystem="2.16.840.1.113883.6.96"
      displayName="Francisella tularensis"/> <!-- Test result -->
    <performer>
      <time value="20090508"/> <!-- Date of test on specimen -->
      <assignedEntity>
        <id nullFlavor="NI"/>
      </assignedEntity>
    </performer>
    <participant typeCode="SBJ">
      <participantRole classCode="ISLT">
        <id root="63af5c4e-2b78-4d41-bd38-9c3caaf86d64"/>
        <playingEntity>
          <code code="51526001" codeSystem="2.16.840.1.113883.6.96"
            displayName="Francisella tularensis"/>
        </playingEntity>
      </participantRole>
    </participant>
    <entryRelationship typeCode="COMP">
      ...
    </entryRelationship>
    ...
  </observation>
</component>
```

## 4.10 CCD Result organizer

[organizer: templateId 2.16.840.1.113883.10.20.1.32]

The result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

1. The value for "Organizer / @moodCode" in a result organizer SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 928).
2. A result organizer SHALL contain at least one Organizer / id. (CONF: 929).
3. A result organizer SHALL contain exactly one Organizer / statusCode. (CONF: 930).
4. A result organizer SHALL contain exactly one Organizer / code. (CONF: 931).
5. The value for "Organizer / code" in a result organizer SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF: 932).



6. A result organizer SHOULD include one or more Organizer / specimen if the specimen isn't inherent in Organizer / code. (CONF: 933).
7. Organizer / specimen SHALL NOT conflict with the specimen inherent in Organizer / code. (CONF: 934).
8. Organizer / specimen / specimenRole / id SHOULD be set to equal a Procedure / specimen / specimenRole / id (see section 3.14 Procedures) to indicate that the Results and the Procedure are referring to the same specimen. (CONF: 935).
9. A result organizer SHALL contain one or more Organizer / component. (CONF: 936).
10. The target of one or more result organizer Organizer / component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in Organizer / code or if there is a need to further specialize the Organizer / code value. (CONF: 937).
11. A result organizer Organizer / component / procedure MAY be a reference to a procedure described in the Procedure section. (See section 5.3 InternalCCRLink for more on referencing within CCD). (CONF: 938).
12. The target of one or more result organizer Organizer / component relationships SHALL be a result observation. (CONF: 939).
13. A result organizer SHALL contain one or more sources of information, as defined in section 5.2 Source. (CONF: 940).

#### 4.10.1 PHCR Result organizer

[organizer: templateId 2.16.840.1.113883.10.20.15.3.59]

The PHCR result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen. Note: Where there is a specimen, one can set the specimenRole/id to equal the specimen collection procedure's participantRole[@classCode="SPEC"]/id in order to assert that this observation is being made on the specimen collected in the corresponding specimen collection procedure.

1. Conforms to CCD Result organizer Template (templateId: 2.16.840.1.113883.10.20.1.32).
2. **SHALL** contain [1..1] **@classCode**="BATTERY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1996)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1997)
4. **SHALL** contain [1..\*] **id** (CONF:1998)
5. **SHALL** contain [1..1] **code/@code** (CONF:1999)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2000)
7. **SHALL** contain [1..1] **effectiveTime** (CONF:2001)
8. **MAY** contain [0..1] **specimen** (CONF:2002), which if present
  - a. **SHOULD** contain [0..1] **specimenRole** (CONF:2003), which if present
    - i. **SHOULD** contain [0..1] **id** (CONF:2004)
    - ii. **SHALL** contain [1..1] **specimenPlayingEntity** (CONF:2005), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:2006)
9. **SHALL** contain [1..\*] **component** (CONF:2007) (specialized branch), which

- a. **SHALL** contain [1..1] **PHCR Result observation**  
(templateId:2.16.840.1.113883.10.20.15.3.58) (CONF:2008)
- 10. **MAY** contain [0..\*] **component** (CONF:2009) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **Specimen collection procedure**  
(templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:2010)

#### 4.10.1.1 Anthrax result organizer

[organizer: templateId 2.16.840.1.113883.10.20.15.3.40]

The anthrax result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.

1. Conforms to PHCR Result organizer Template (templateId: 2.16.840.1.113883.10.20.15.3.59).
2. **SHALL** contain [1..1] **@classCode**="BATTERY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1425)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1426)
4. **SHALL** contain [1..\*] **id** (CONF:1427)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3207 Lab Test Result Name (Anthrax) **DYNAMIC** (CONF:1428)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1429)
7. **SHALL** contain [1..1] **effectiveTime** (CONF:1430)
8. **MAY** contain [0..1] **specimen** (CONF:1431), which if present
  - a. **SHOULD** contain [0..1] **specimenRole** (CONF:1432), which if present
    - i. **SHOULD** contain [0..1] **id** (CONF:1433)
    - ii. **SHALL** contain [1..1] **specimenPlayingEntity** (CONF:1434), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1435)
9. **MAY** contain [0..\*] **component** (CONF:1436) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **Anthrax result observation**  
(templateId:2.16.840.1.113883.10.20.15.3.39) (CONF:1437)
10. **SHALL** contain [1..\*] **component** (CONF:1438) (specialized branch), which
  - a. **SHALL** contain [1..1] **Specimen collection procedure**  
(templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1439)

**Figure 40: Anthrax result organizer example**

```
<entry typeCode="DRIV">
  <!-- Anthrax Result Organizer -->
  <organizer classCode="BATTERY" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.40"/>
    <id nullFlavor="NI"/>
    <code code="225997002" codeSystem="2.16.840.1.113883.6.96"
      displayName="Taking wound swab"/>
    <statusCode code="completed"/>
    <effectiveTime value="20090309"/>
    <!-- Specimen collection date-->

    <specimen>
      <specimenRole>
        <id root="1dec3000-081f-11de-8c30-0800200c9a66"/>
        <specimenPlayingEntity>
          <code code="258505006" codeSystem="2.16.840.1.113883.6.96"
            displayName="Skin ulcer swab"/> </code>
          <!-- Specimen type -->
        </specimenPlayingEntity>
      </specimenRole>
    </specimen>

    <component>
      <!-- Anthrax Result Observation -->
      <observation classCode="OBS" moodCode="EVN">
        ...
      </observation>
    </component>
    ...
  </organizer>
</entry>
```

#### 4.10.1.2 Tuberculosis result organizer

[organizer: templateId 2.16.840.1.113883.10.20.15.3.21]

The tuberculosis result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.

1. Conforms to PHCR Result organizer Template (templateId: 2.16.840.1.113883.10.20.15.3.59).
2. **SHALL** contain [1..1] **@classCode**="BATTERY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:949)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:950)
4. **SHALL** contain [1..\*] **id** (CONF:951)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) **DYNAMIC** (CONF:952)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:953)

7. **SHALL** contain [1..1] **effectiveTime** (CONF:954)
8. **MAY** contain [0..1] **specimen** (CONF:956), which if present
  - a. **SHOULD** contain [0..1] **specimenRole** (CONF:957), which if present
    - i. **SHOULD** contain [0..1] **id** (CONF:958)
    - ii. **SHALL** contain [1..1] **specimenPlayingEntity** (CONF:959), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:960)
9. **SHALL** contain [1..\*] **component** (CONF:1231) (specialized branch), which
  - a. **SHALL** contain [1..1] **Tuberculosis result observation** (templateId:2.16.840.1.113883.10.20.15.3.13) (CONF:1232)
10. **MAY** contain [0..\*] **component** (CONF:972) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:974)

**Figure 41: Tuberculosis result organizer example**

```

<entry typeCode="DRIV">
  <!-- TB Result Organizer -->
  <organizer classCode="BATTERY" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.21"/>
    <id nullFlavor="NI"/>
    <code code="104173009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Sputum culture"/>
    <statusCode code="completed" />
    <effectiveTime value="20081215"/> <!-- Specimen collection date-->

    <specimen>
      <specimenRole>
        <id root="d5a9ef50-d05e-11dd-ad8b-0800200c9a66"/>
        <specimenPlayingEntity>
          <code code="45710003" codeSystem="2.16.840.1.113883.6.96"
            displayName="Sputum"> </code> <!-- Specimen type -->
          </specimenPlayingEntity>
        </specimenRole>
      </specimen>

      <component>
        ...
      </component>

      ...
    </organizer>
  </entry>

```

#### 4.10.1.3 Tularemia result organizer

[organizer: templateId 2.16.840.1.113883.10.20.15.3.52]

The tularemia result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen

1. Conforms to PHCR Result organizer Template (templateId: 2.16.840.1.113883.10.20.15.3.59).
2. **SHALL** contain [1..1] **@classCode**="BATTERY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1814)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1815)
4. **SHALL** contain [1..\*] **id** (CONF:1816)
5. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3208 Lab Test Result Name (Tularemia) **DYNAMIC** (CONF:1817)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1818)
7. **SHALL** contain [1..1] **effectiveTime** (CONF:1819)
8. **MAY** contain [0..1] **specimen** (CONF:1820), which if present
  - a. **SHOULD** contain [0..1] **specimenRole** (CONF:1821), which if present
    - i. **SHOULD** contain [0..1] **id** (CONF:1822)
    - ii. **SHALL** contain [1..1] **specimenPlayingEntity** (CONF:1823), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:1824)
9. **SHALL** contain [1..\*] **component** (CONF:1825) (specialized branch), which
  - a. **SHALL** contain [1..1] **Tularemia result observation** (templateId:2.16.840.1.113883.10.20.15.3.51) (CONF:1826)
10. **MAY** contain [0..\*] **component** (CONF:1827) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **Specimen collection procedure** (templateId:2.16.840.1.113883.10.20.15.3.2) (CONF:1828)

**Figure 42: Tularemia result organizer example**

```
<entry typeCode="DRIV">
  <!-- Tularemia Result Organizer -->
  <organizer classCode="BATTERY" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.52"/>
    <id nullFlavor="NI"/>
    <code code="30088009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Blood culture"/>
    <statusCode code="completed" />
    <effectiveTime value="20090508"/> <!-- Specimen collection date-->
    <specimen>
      <specimenRole>
        <id root="1dec3000-081f-11de-8c30-0800200c9a66"/>
        <specimenPlayingEntity>
          <code code="119297000" codeSystem="2.16.840.1.113883.6.96"
            displayName="Blood specimen"> </code>
          <!-- Specimen type -->
        </specimenPlayingEntity>
      </specimenRole>
    </specimen>

    <component>
      <observation>
        ...
      </observation>
      ...
    </component>
    ...
  </organizer>
</entry>
```

## 4.11 CCD Social history observation

[observation: templateId 2.16.840.1.113883.10.20.1.33]

This clinical statement represents the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity, and religious affiliation.

1. The value for "Observation / @classCode" in a social history observation SHALL be "OBS" 2.16.840.1.113883.5.6 ActClass STATIC. (CONF: 883).
2. The value for "Observation / @moodCode" in a social history observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 884).
3. A social history observation SHALL contain at least one Observation / id. (CONF: 885).
4. A social history observation SHALL include exactly one Observation / statusCode. (CONF: 886).
5. The value for "Observation / statusCode" in a social history observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 887).
6. The value for "Observation / code" in a social history observation SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode STATIC 20061017. (CONF: 888).

7. Observation / value can be any datatype. Where Observation / value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF: 889).
8. A social history observation SHALL contain one or more sources of information, as defined in section 5.2 Source. (CONF: 890).

#### 4.11.1.1 Acute hepatitis B socio-behavioral boolean risk factor

[observation: templateId 2.16.840.1.113883.10.20.15.3.28]

This clinical statement represents whether or not specific socio-behavioral risk factors were engaged in by the patient that are pertinent to hepatitis B. The information should be sent if it is known that the patient engaged in one or more of these socio-behavioral risk factors and may be sent if explicitly known that the patient did NOT engage in one or more of these socio-behavioral risk factors.

1. Conforms to CCD Social history observation Template (templateId: 2.16.840.1.113883.10.20.1.33).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1101)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1102)
4. **SHALL** contain **@negationInd** (CONF:1103)
5. **SHALL** contain [1..\*] **id** (CONF:1104)
6. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1105)
7. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1106)
8. **SHOULD** contain [0..1] **effectiveTime** (CONF:1107)
9. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3228 Sociobehavioral risk factor **DYNAMIC** (CONF:1108)

**Figure 43: Acute hepatitis B socio-behavioral boolean risk factor example**

```
<!-- Shared razor, toothbrushes or nail care items Yes/No Observation -->
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.28" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime value="200809"/>
    <value xsi:type="CD" code="55211-7" codeSystem="2.16.840.1.113883.6.1"
      displayName=" Shared razor, toothbrushes or nail care items" />
  </observation>
</entry>
```

#### 4.11.2 Tuberculosis socio-behavioral boolean risk factor

[observation: templateId 2.16.840.1.113883.10.20.15.3.15]

This clinical statement represents the specific socio-behavioral risk factors engaged in by the patient that are pertinent to tuberculosis. The information should be sent if it is known that the patient engaged in one or more of these socio-behavioral risk factors and may be sent if explicitly known that the patient did NOT engage in one or more of these socio-behavioral risk factors.

1. Conforms to CCD Social history observation Template (templateId: 2.16.840.1.113883.10.20.1.33).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:868)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:869)
4. **SHALL** contain **@negationInd** (CONF:874)
5. **SHALL** contain [1..\*] **id** (CONF:891)
6. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:870)
7. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:871)
8. **SHOULD** contain [0..1] **effectiveTime** (CONF:872)
9. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3228 Sociobehavioral risk factor **DYNAMIC** (CONF:873)

**Figure 44: Tuberculosis socio-behavioral boolean risk factor example**

```
<entry typeCode="DRIV">
  <!-- Homeless within the past year observation-->
  <observation classCode="OBS" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.15"/>
    <id nullFlavor="NI"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="20080110" />
      <high value="20090110" />
    </effectiveTime>
    <value xsi:type="CD" code="32911000" codeSystem="2.16.840.1.113883.6.96"
      displayName="Homeless"/>
  </observation>
</entry>
```



## 4.12 CCD Status observation

[observation: templateId 2.16.840.1.113883.10.20.1.57]

This clinical statement represents the state of an observation.

1. A status observation SHALL be the target of an entryRelationship whose value for “entryRelationship / @typeCode” SHALL be “REFR” 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF: 492).
2. The value for “Observation / @classCode” in a status observation SHALL be “OBS” 2.16.840.1.113883.5.6 ActClass STATIC. (CONF: 493).
3. The value for “Observation / @moodCode” in a status observation SHALL be “EVN” 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 494).
4. A status observation SHALL contain exactly one Observation / code. (CONF: 495).
5. The value for “Observation / code” in a status observation SHALL be “33999-4” “Status” 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 496).
6. A status observation SHALL contain exactly one Observation / statusCode. (CONF: 497).
7. The value for “Observation / statusCode” in a status observation SHALL be “completed” 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 498).
8. A status observation SHALL contain exactly one Observation / value, which SHALL be of datatype “CE”. (CONF: 499).
9. status observation SHALL NOT contain any additional Observation attributes. (CONF: 500).
10. A status observation SHALL NOT contain any Observation participants. (CONF: 501).
11. A status observation SHALL NOT be the source of any Observation relationships. (CONF: 502).

### 4.12.1 CCD Medication status observation

[observation: templateId 2.16.840.1.113883.10.20.1.47]

This clinical statement represents the patient’s medication status such as “active” or “on hold”.

1. Conforms to CCD Status observation Template (templateId: 2.16.840.1.113883.10.20.1.57).
2. The value for “Observation / value” in a medication status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode STATIC 20061017. (CONF: 1026).
3. A medication activity SHALL contain exactly one SubstanceAdministration / consumable, the target of which is a product template. (CONF: 1027).
4. A medication activity MAY contain exactly one medication series number observations. (CONF: 1028).

#### 4.12.2 CCD Problem status observation

[observation: templateId 2.16.840.1.113883.10.20.1.50]

ASTM CCR, in addition to the status observations defined in many sections, defines a restricted set of optional healthstatus values (“Alive And Well”, “In Remission”, “Symptom Free”, “Chronically Ill”, “Severely Ill”, “Disabled”, “Severely Disabled”, “Deceased”) that describe the status of the patient overall as a result of a particular problem, represented in CCD as an associated problem healthstatus observation.

1. Conforms to CCD Status observation Template (templateId: 2.16.840.1.113883.10.20.1.57).
2. The value for “Observation / value” in a problem status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017. (CONF: 508).
3. A problem observation MAY contain exactly one problem healthstatus observation. (CONF: 509).
4. A problem healthstatus observation (templateId 2.16.840.1.113883.10.20.1.51) SHALL be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section 5.1 “Type” and “Status” values), except that the value for “Observation / code” in a problem healthstatus observation SHALL be “11323-3” “Health status” 2.16.840.1.113883.6.1 LOINC STATIC. (CONF: 510).
5. The value for “Observation / value” in a problem healthstatus observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017. (CONF: 511).

#### 4.13 Estimated date of delivery

[observation: templateId 2.16.840.1.113883.10.20.15.3.1]

This clinical statement represents the anticipated date when a woman will give birth.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:444)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:445)
3. **SHALL** contain [1..1] **code/@code**="11778-8" *Estimated date of delivery* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:446)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:448)
5. **SHALL** contain [1..1] **value** (TS) (CONF:450)

**Figure 45: Estimated date of delivery example**

```
<entryRelationship typeCode="REFR">
  <!-- Estimated date of Delivery entry -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.1" />
    <code code="11778-8" codeSystem="2.16.840.1.113883.6.1"
      displayName="Estimated delivery date" />
    <statusCode code="completed" />
    <value xsi:type="TS" value="20090215" />
  </observation>
</entryRelationship>
```

## 4.14 Geotemporal history observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.3]

This clinical statement represents locations within or out of the US that are potentially relevant to current condition. A text element is available for embellishing the observation.

1. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:420)
2. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:421)
3. **SHALL** contain [1..1] **code/@code="55210-9"** *Geotemporal History* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:422)
4. **MAY** contain [0..1] **text** (CONF:1287)
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:423)
6. **SHOULD** contain [0..1] **effectiveTime** (CONF:424)
7. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3201 Geographical location history **DYNAMIC** (CONF:425)

**Figure 46: Geotemporal history observation example**

```
<entry typeCode="DRIV">
  <!-- Geotemporal History Observations-->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.3"/>
    <code code="55210-9" codeSystem="2.16.840.1.113883.6.1"
      displayName="Geotemporal History"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="1985"/>
      <high value="1993"/>
    </effectiveTime>
    <value xsi:type="CD" code="THA" codeSystem="1.0.3166.1"
      displayName="Thailand"/>
  </observation>
</entry>
```

## 4.15 HIV status observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.4]

This clinical statement represents the patient's human immunodeficiency (HIV) status.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:861)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:862)
3. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:864)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:865)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:866)
6. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3232 HIV Status **DYNAMIC** (CONF:867)

**Figure 47: HIV status observation example**

```
<entry typeCode="DRIV">
  <!-- HIV status observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.4" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime value="20090110"/> <!-- status as of date of report -->
    <value xsi:type="CD" code="165815009" codeSystem="2.16.840.1.113883.6.96"
      displayName="HIV negative"/>
  </observation>
</entry>
```

## 4.16 Job related body fluid exposure risk frequency

[observation: templateId 2.16.840.1.113883.10.20.15.3.29]

This clinical statement represents how often the subject of the case report is exposed to blood or body fluids through his/her job.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1109)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1110)
3. **SHALL** contain [1..1] **code/@code**="55212-5" *Occupation related direct blood or body fluid exposure frequency* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:1111)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1112)
5. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3225 Blood or body fluid exposure frequency **DYNAMIC** (CONF:1114)

**Figure 48: Job-related body fluid exposure risk frequency example**

```
<entry typeCode="DRIV">
  <!-- Job Related Body fluid exposure risk frequency -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.29" />
    <code code="55212-5" codeSystem="2.16.840.1.113883.6.1"
      displayName="Occupation related direct blood or body
      fluid exposure frequency" />
    <statusCode code="completed" />
    <value xsi:type="CD" code="70232002" codeSystem="2.16.840.1.113883.6.96"
      displayName="Frequent" />
  </observation>
</entry>
```

## 4.17 Location of lesion observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.44]

This clinical statement represents a way to more specifically identify where the tularemia lesions are located. The specific disease name often identifies the general location of where the lesions are (e.g., Oropharyngeal tularemia); however, the provider may wish to provide added details.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1672)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1673)
3. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1675)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1676)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:1677)
6. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3213 Signs and Symptoms (Acute Hepatitis B) **DYNAMIC** (CONF:1678)
7. **SHALL** contain [1..\*] **targetSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:1679)

**Figure 49: Location of lesion observation example**

```
<entryRelationship typeCode="MFST" inversionInd="true">
  <!-- Location of lesion(s) observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.44"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20090509" />
    </effectiveTime>
    <value xsi:type="CD" code="49755003" codeSystem="2.16.840.1.113883.6.96"
      displayName="Lesion" />
    <targetSiteCode code="85151006" codeSystem="2.16.840.1.113883.6.96"
      displayName="Left Hand"/>
    <targetSiteCode code="78791008" codeSystem="2.16.840.1.113883.6.96"
      displayName="Right Hand"/>
    <targetSiteCode code="64262003" codeSystem="2.16.840.1.113883.6.96"
      displayName="Right forearm"/>
  </observation>
</entryRelationship>
```

#### 4.18 Most recent time arrived in USA observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.6]

This clinical statement represents the date that the subject most recently arrived into the US.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:426)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:427)
3. **SHALL** contain [1..1] **code/@code**="55209-1" *Most recent time arrived in USA* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:428)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:429)
5. **SHALL** contain [1..1] **value** (TS)(CONF:431)

**Figure 50: Most recent time arrived in USA observation example**

```
<entry typeCode="DRIV">
  <!-- Most recent time arrived in USA observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.6"/>
    <code code="55209-1" codeSystem="2.16.840.1.113883.6.1"
      displayName="Most recent time arrived in USA" />
    <statusCode code="completed"/>
    <value xsi:type="TS" value="20070302" />
  </observation>
</entry>
```

## 4.19 Occupation observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.7]

This clinical statement represents the occupation of the subject of the case report. The values are coded values from the Standard Occupational Classification (SOC) system used by federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. A text element is available for embellishing the observation. The template allows for representation of the name and address of the employer. As much detail should be entered as possible. This information is used by public health departments in their investigation to determine the occupation of the subject of the case report. An observation of occupation may be negated (e.g., not a Healthcare Worker) if it is specifically known that the subject of the case report did or does NOT hold an occupation of interest/risk. In addition, this template allows for the representation of the related industry using codes from the Industry (NAICS).

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:437)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:438)
3. **MAY** contain **@negationInd** (CONF:1284)
4. **SHALL** contain [1..1] **code/@code**="11341-5" *History of occupation* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:439)
5. **MAY** contain [0..1] **text** (CONF:442)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:440)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:443)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.887 Occupation **DYNAMIC** (CONF:441)
9. **MAY** contain [0..1] **participant** (CONF:2170) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:2171)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:2173), which
    - i. **SHALL** contain [1..1] **@classCode**="LOCE" *Located entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:2174)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:2175)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:2176)
    - iv. **SHOULD** contain [0..1] **playingEntity** (CONF:2177), which if present
      1. **SHALL** contain [1..1] **@classCode**="PLC" *Place* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:2178)
      2. **SHOULD** contain [0..\*] **name** (CONF:2179)
10. **SHOULD** contain [0..1] **entryRelationship** (CONF:2180) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2181)
  - b. **SHALL** contain [0..\*] **observation** (CONF:2191), which if present
    - i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2182)

- ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2183)
- iii. **SHALL** contain [1..1] **code/@code**="21844-6" *Industry Hx* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:2185)
- iv. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2187)
- v. **SHOULD** contain [0..1] **effectiveTime** (CONF:2188)
- vi. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1100 Industry (NAICS) **DYNAMIC** (CONF:2189)



**Figure 51: Occupation and industry type observation example**

```
<entry typeCode="DRIV">
  <!-- Occupation observation -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.7" />
    <code code="11341-5" codeSystem="2.16.840.1.113883.6.1"
    displayName="History of occupation" />
    <!-- Embellish the type of work here -->
    <text>The patient shears sheep.</text>
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20080110" />
      <high value="20090110" />
    </effectiveTime>
    <value xsi:type="CD" code="45-2093" codeSystem="2.16.840.1.113883.6.243"
      displayName="Farmworkers, Farm and Ranch Animals" />
    <participant typeCode="LOC">
      <!-- Occupation address -->
      <participantRole classCode="LOCE">
        <addr>
          <streetAddressLine>1000 Mountain Way</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <playingEntity classCode="PLC">
          <name>Zzzz Agribusiness</name>
        </playingEntity>
      </participantRole>
    </participant>
    <entryRelationship typeCode="REFR">
      <!-- Industry type observation -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="21844-6" codeSystem="2.16.840.1.113883.6.1"
        displayName="Industry Hx" />
        <statusCode code="completed" />
        <effectiveTime>
          <low value="20080110" />
          <high value="20090110" />
        </effectiveTime>
        <value xsi:type="CD" code="112410" codeSystem="2.16.840.1.113883.6.85"
          displayName="Sheep Farming" />
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

## 4.20 Patient condition – alive

[observation: templateId 2.16.840.1.113883.10.20.15.3.42]

This clinical statement represents the observation that the subject of the case report was alive at the time of the report.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1591)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1592)
3. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1593)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1594)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:1595)
6. **SHALL** contain [1..1] **value/@code**="438949009" *Alive* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1597)

**Figure 52: Patient condition – alive example**

```
<entry typeCode="DRIV">
  <!-- Patient condition - alive-->
  <observation classCode="OBS" moodCode="EVN" >
    <templateId root="2.16.840.1.113883.10.20.15.3.42"/>
    <id nullFlavor="NI"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <high value="20090110" />
    </effectiveTime>
    <value xsi:type="CD" code="438949009"
      codeSystem="2.16.840.1.113883.6.96" displayName="Alive"/>
  </observation>
</entry>
```

## 4.21 Patient condition – deceased

[observation: templateId 2.16.840.1.113883.10.20.15.3.17]

This clinical statement represents the observation that the subject of the case report was deceased at the time of the report. It also represents if the death was caused by the condition being reported. The entryRelationship type of CAUS provides the link together with the observation/id and observation value as to whether or not the condition caused the death. A negationIndicator of false means the condition caused the death. A negationIndicator of true means the condition did not cause the death.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:482)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:483)

3. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:485)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:486)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:487), which if present
  - a. effectiveTime/low SHALL equal the time of death (CONF:490).
6. **SHALL** contain [1..1] **value/@code**="419099009" *Dead* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:488)
7. **SHALL** contain [1..1] **entryRelationship** ([CONF:1581](#)) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="CAUS" *Is etiology for* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1582)
  - b. **SHALL** contain **@negationInd** (CONF:1583)
  - c. **SHALL** contain [1..1] **observation** (CONF:1584), which
    - i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1585)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1586)
    - iii. SHALL contain 1..1 id/@root which SHALL equal the case observation/id (CONF:1587).
    - iv. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1588)
    - v. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1589)
    - vi. SHALL contain 1..1 value which SHALL equal the case observation/value (CONF:1590).

**Figure 53: Patient condition – deceased example**

```
<entry typeCode="DRIV">
  <!-- Patient condition - deceased - this example shows the patient died and the
  cause was TB. If the patient was dead and the cause was not TB, the
  negation indicator on the entryRelationship type "caus" would be "true"-->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.17"/>
    <id nullFlavor="NI"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="20081231" />
    </effectiveTime>
    <value xsi:type="CD" code="419099009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Dead"/>
    <entryRelationship typeCode="CAUS" negationInd="false">
      <observation classCode="OBS" moodCode="EVN">
        <id root="d11275e7-67ae-11db-bd13-0800200c9a66" />
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
        <statusCode code="completed" />
        <value xsi:type="CD" code="56717001" codeSystem="2.16.840.1.113883.6.96"
          displayName="Tuberculosis" />
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

## 4.22 PHCR Signs and symptoms

[observation: templateId 2.16.840.1.113883.10.20.15.3.53]

This clinical statement is available to represent the signs and symptoms that are associated with the condition. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1861)
2. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1862)
3. **SHALL** contain **@negationInd** (CONF:1863)
4. **SHALL** contain [1..1] **code/@code="ASSERTION"** (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1864)
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1865)
6. **SHOULD** contain [0..1] **effectiveTime** (CONF:1866)
7. **SHALL** contain [1..1] **value/@code** (CONF:1867)

#### 4.22.1 Acute hepatitis B signs and symptoms

[observation: templateId 2.16.840.1.113883.10.20.15.3.22]

This clinical statement represents the signs and symptoms that are typically associated with acute hepatitis B. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. Conforms to PHCR signs and symptoms Template (templateId: 2.16.840.1.113883.10.20.15.3.53).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:982)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:983)
4. **SHALL** contain **@negationInd** (CONF:984)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:985)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:986)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:987)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3213 Signs and Symptoms (Acute Hepatitis B) **DYNAMIC** (CONF:988)

**Figure 54: Acute hepatitis B signs and symptoms example**

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    ...
    <!-- Jaundice observation -->
    <entryRelationship typeCode="MFST" inversionInd="true">
      <observation classCode="OBS" moodCode="EVN" negationInd="false">
        <templateId root="2.16.840.1.113883.10.20.15.3.22" />
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
        <statusCode code="completed" />
        <effectiveTime>
          <low value="20081226" />
          <!-- Date of onset of symptom -->
        </effectiveTime>
        <value xsi:type="CD" code="18165001" codeSystem="2.16.840.1.113883.6.96"
          displayName="Jaundice" />
      </observation>
    </entryRelationship>
  </observation>
  ...
</entry>
```

### 4.22.2 Anthrax signs and symptoms

[observation: templateId 2.16.840.1.113883.10.20.15.3.35]

This clinical statement represents the signs and symptoms that are typically associated with anthrax. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. Conforms to PHCR signs and symptoms Template (templateId: 2.16.840.1.113883.10.20.15.3.53).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1288)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1289)
4. **SHALL** contain **@negationInd** (CONF:1290)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1291)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1292)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1293)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3212 Signs and Symptoms (Anthrax) **DYNAMIC** (CONF:1294)

**Figure 55: Anthrax signs and symptoms example**

```
<entryRelationship typeCode="MFST" inversionInd="true">
  <!-- Anthrax Signs and Symptoms -->
  <!-- Asymptomatic observation -->
  <observation classCode="OBS" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.35"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" code="84387000" codeSystem="2.16.840.1.113883.6.96"
      displayName="Asymptomatic"/>
  </observation>
</entryRelationship>
```

### 4.22.3 Tuberculosis signs and symptoms

[observation: templateId 2.16.840.1.113883.10.20.15.3.14]

This clinical statement represents the signs and symptoms that are typically associated with tuberculosis. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. Conforms to PHCR signs and symptoms Template (templateId: 2.16.840.1.113883.10.20.15.3.53).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:677)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:678)
4. **SHALL** contain **@negationInd** (CONF:679)

5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:680)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:681)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:682)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3214 Signs and Symptoms (TB) **DYNAMIC** (CONF:683)

**Figure 56: Tuberculosis signs and symptoms example**

```
entryRelationship typeCode="MFST" inversionInd="true">
  <!-- TB Signs and Symptoms -->
  <!-- Asymptomatic observation -->
  <observation classCode="OBS" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.14"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <value xsi:type="CD" code="84387000" codeSystem="2.16.840.1.113883.6.96"
      displayName="Asymptomatic" />
  </observation>
</entryRelationship>
```

#### 4.22.4 Tularemia signs and symptoms

[observation: templateId 2.16.840.1.113883.10.20.15.3.45]

This clinical statement represents the signs and symptoms that are typically associated with tularemia. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. Conforms to PHCR signs and symptoms Template (templateId: 2.16.840.1.113883.10.20.15.3.53).
2. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1680)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1681)
4. **SHALL** contain **@negationInd** (CONF:1682)
5. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1683)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1684)
7. **SHOULD** contain [0..1] **effectiveTime** (CONF:1685)
8. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3215 Signs and Symptoms (Tularemia) **DYNAMIC** (CONF:1686)

**Figure 57: Tularemia signs and symptoms example**

```
<entryRelationship typeCode="MFST" inversionInd="true">
  <!-- tularemia Signs and Symptoms (One template with valueset)-->
  <!-- Asymptomatic observation -->
  <observation classCode="OBS" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.45"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
    <value xsi:type="CD" code="84387000" codeSystem="2.16.840.1.113883.6.96"
      displayName="Asymptomatic" />
  </observation>
</entryRelationship>
```

## 4.23 PHCR Therapeutic regimen

[act: templateId 2.16.840.1.113883.10.20.15.3.57]

This clinical statement represents if treatment was administered for the reported condition. A negationInd "false" means treatment was given. A negationInd "true" means treatment was not given. If treatment(s) were given, they should be reflected in corresponding "PHCR treatment given" template(s). "PHCR treatment not given" templates may also be present.

1. **SHALL** contain [1..1] **@classCode="ACT"** (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1940)
2. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1941)
3. **SHALL** contain **@negationInd** (CONF:1942)
4. **SHALL** contain [1..1] **code/@code="133877004"** *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1943)
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1944)
6. **SHALL** contain [1..1] **entryRelationship** (CONF:1945) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="REFR"** *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1946)
  - b. **SHALL** contain [1..1] **observation** (CONF:1947), which
    - i. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1948)
    - ii. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1949)
    - iii. observation/id SHALL be present, and SHALL equal case observation's observation/id (CONF:1950).
    - iv. **SHALL** contain [1..1] **code/@code="ASSERTION"** (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1951)
    - v. **SHALL** contain [1..1] **value/@code** (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:1952)
7. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1953) (specialized branch), which if present



- a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1954)
- b. **SHALL** contain [1..1] **PHCR Treatment given** (templateId:2.16.840.1.113883.10.20.15.3.55) (CONF:1955)
- 8. **MAY** contain [0..\*] **entryRelationship** (CONF:1956) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1957)
  - b. **SHALL** contain [1..1] **PHCR Treatment not given** (templateId:2.16.840.1.113883.10.20.15.3.56) (CONF:1958)

#### 4.23.1 Acute hepatitis B therapeutic regimen

[act: templateId 2.16.840.1.113883.10.20.15.3.23]

This clinical statement represents if treatment was administered for acute hepatitis B. A negationInd of "false" means treatment was given. A negationInd of true" means treatment was not given.

- 1. Conforms to PHCR Therapeutic regimen Template (templateId: 2.16.840.1.113883.10.20.15.3.57).
- 2. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:989)
- 3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:990)
- 4. **SHALL** contain **@negationInd** (CONF:991)
- 5. **SHALL** contain [1..1] **code/@code**="133877004" *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:992)
- 6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:993)
- 7. **SHALL** contain [1..1] **entryRelationship** (CONF:994) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:995)
  - b. **SHALL** contain [1..1] **observation** (CONF:996), which
    - i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:997)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:998)
    - iii. observation/id SHALL be present, and SHALL equal Hep B case observation's observation/id (CONF:999).
    - iv. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1000)
    - v. **SHALL** contain [1..1] **value/@code**="76795007" *Acute hepatitis B* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1001)

**Figure 58: Acute hepatitis B therapeutic regimen example**

```
<!-- Hep B therapeutic regimen -->
<entry typeCode="DRIV">
  <act classCode="ACT" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.23" />
    <code code="133877004" codeSystem="2.16.840.1.113883.6.96"
      displayName="Therapeutic regimen" />
    <statusCode code="completed" />
    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <id root="d11275e7-67ae-11db-bd13-0800200c9a66" />
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
        <value xsi:type="CD" code="76795007" codeSystem="2.16.840.1.113883.6.96"
          displayName="Acute hepatitis B" />
      </observation>
    </entryRelationship>
  </act>
</entry>
```

#### 4.23.2 Anthrax therapeutic regimen

[act: templateId 2.16.840.1.113883.10.20.15.3.37]

This clinical statement represents if treatment was administered for anthrax. A negationInd "false" means treatment was given. A negationInd "true" means treatment was not given. If treatment(s) were given, they should be reflected in corresponding anthrax treatment given template(s). Anthrax treatment not given templates may also be present.

1. Conforms to PHCR Therapeutic regimen Template (templateId: 2.16.840.1.113883.10.20.15.3.57).
2. **SHALL** contain [1..1] **@classCode="ACT"** (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1324)
3. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1325)
4. **SHALL** contain **@negationInd** (CONF:1326)
5. **SHALL** contain [1..1] **code/@code="133877004"** *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1327)
6. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1328)
7. **SHALL** contain [1..1] **entryRelationship** (CONF:1329) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="REFR"** *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1330)
  - b. **SHALL** contain [1..1] **observation** (CONF:1331), which
    - i. **SHALL** contain [1..1] **@classCode="OBS"** *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1332)
    - ii. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1333)
    - iii. observation/id SHALL be present, and SHALL equal Anthrax case observation's observation/id (CONF:1334).

- iv. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1335)
- v. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3220 Disease Type (Anthrax) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:1336)
- 8. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1349) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1350)
  - b. **SHALL** contain [1..1] **Anthrax treatment given** (templateId:2.16.840.1.113883.10.20.15.3.38) (CONF:1351)
- 9. **MAY** contain [0..\*] **entryRelationship** (CONF:1775) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1776)
  - b. **SHALL** contain [1..1] **Anthrax treatment not given** (templateId:2.16.840.1.113883.10.20.15.3.49) (CONF:1777)

**Figure 59: Anthrax therapeutic regimen example**

```
<entry typeCode="DRIV">
  <!-- Anthrax therapeutic regimen -->
  <act classCode="ACT" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.37"/>
    <code code="133877004" codeSystem="2.16.840.1.113883.6.96"
      displayName="Therapeutic regimen"/>
    <statusCode code="completed"/>

    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <id root="d9f34320-0814-11de-8c30-0800200c9a66"/>
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
        <value xsi:type="CD" code="84980006" codeSystem="2.16.840.1.113883.6.96"
          displayName="Cutaneous anthrax"/>
      </observation>
    </entryRelationship>

    <entryRelationship>
      ...
    </entryRelationship>
  </act>
</entry>
```

### 4.23.3 Tuberculosis therapeutic regimen

[act: templateId 2.16.840.1.113883.10.20.15.3.18]

This clinical statement represents if treatment was administered for tuberculosis. A negationInd "false" means treatment was given. A negationInd "true" means treatment was not given. If treatment(s) were given, they should be reflected in corresponding tuberculosis treatment given template(s). Tuberculosis treatment not given templates may also be present.

1. Conforms to PHCR Therapeutic regimen Template (templateId: 2.16.840.1.113883.10.20.15.3.57).
2. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:635)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:636)
4. **SHALL** contain **@negationInd** (CONF:637)
5. **SHALL** contain [1..1] **code/@code**="133877004" *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:650)
6. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:651)
7. **SHALL** contain [1..1] **entryRelationship** (CONF:652) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:653)
  - b. **SHALL** contain [1..1] **observation** (CONF:654), which
    - i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:646)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:647)
    - iii. observation/id SHALL be present, and SHALL equal the tuberculosis case observation's observation/id (CONF:648).
    - iv. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:655)
    - v. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3222 Disease Type (TB) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:649)
8. **SHOULD** contain [0..\*] **entryRelationship** (CONF:656) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:657)
  - b. **SHALL** contain [1..1] **Tuberculosis treatment given** (templateId:2.16.840.1.113883.10.20.15.3.16) (CONF:658)
9. **MAY** contain [0..\*] **entryRelationship** (CONF:659) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:660)
  - b. **SHALL** contain [1..1] **Tuberculosis treatment not given** (templateId:2.16.840.1.113883.10.20.15.3.19) (CONF:661)

**Figure 60: Tuberculosis therapeutic regimen example**

```
<entry typeCode="DRIV">
  <!-- TB therapeutic regimen -->
  <act classCode="ACT" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.18"/>
    <code code="133877004" codeSystem="2.16.840.1.113883.6.96"
      displayName="Therapeutic regimen"/>
    <statusCode code="completed"/>
    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <id root="d11275e7-67ae-11db-bd13-0800200c9a66" />
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
        <value xsi:type="CD" code="56717001"
          codeSystem="2.16.840.1.113883.6.96"
          displayName="Tuberculosis" />
      </observation>
    </entryRelationship>
    <entryRelationship>
      <substanceAdministration>
        ...
      </substanceAdministration>
      ...
    </entryRelationship>
    ...
  </act>
</entry>
```

#### 4.23.4 Tularemia therapeutic regimen

[act: templateId 2.16.840.1.113883.10.20.15.3.48]

This clinical statement represents if treatment was administered for tularemia. A negationInd "false" means treatment was given. A negationInd "true" means treatment was not given. If treatment(s) were given, they should be reflected in corresponding tularemia treatment given template(s). Tularemia treatment not given templates may also be present.

1. Conforms to PHCR Therapeutic regimen Template (templateId: 2.16.840.1.113883.10.20.15.3.57).
2. **SHALL** contain [1..1] **@classCode="ACT"** (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1740)
3. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1741)
4. **SHALL** contain **@negationInd** (CONF:1742)
5. **SHALL** contain [1..1] **code/@code="133877004"** *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1743)
6. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1744)
7. **SHALL** contain [1..1] **entryRelationship** (CONF:1745) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode="REFR"** *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1746)
  - b. **SHALL** contain [1..1] **observation** (CONF:1747), which

- i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1748)
  - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1749)
  - iii. observation/id **SHALL** be present, and **SHALL** equal tularemia case observation's observation/id (CONF:1750).
  - iv. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:1751)
  - v. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3223 Disease Type (Tularemia) (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **DYNAMIC** (CONF:1752)
- 8. **SHOULD** contain [0..\*] **entryRelationship** (CONF:1753) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1754)
  - b. **SHALL** contain [1..1] **Tularemia treatment given** (templateId:2.16.840.1.113883.10.20.15.3.47) (CONF:1755)
- 9. **MAY** contain [0..\*] **entryRelationship** (CONF:1778) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:1779)
  - b. **SHALL** contain [1..1] **Tularemia treatment not given** (templateId:2.16.840.1.113883.10.20.15.3.50) (CONF:1780)

**Figure 61: Tularemia therapeutic regimen example**

```
<entry typeCode="DRIV">
  <!-- Tularemia therapeutic regimen -->
  <act classCode="ACT" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.48"/>
    <code code="133877004" codeSystem="2.16.840.1.113883.6.96"
      displayName="Therapeutic regimen"/>
    <statusCode code="completed"/>

    <entryRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <id root="d9f34320-0814-11de-8c30-0800200c9a66" />
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
        <value xsi:type="CD" code="398554008"
          codeSystem="2.16.840.1.113883.6.96"
          displayName="Typhoidal tularemia" />
      </observation>
    </entryRelationship>

    <entryRelationship typeCode="COMP">
      <!-- Tularemia Treatment given -->
      <substanceAdministration classCode="SBADM"
        moodCode="EVN" negationInd="false">
        <templateId root="2.16.840.1.113883.10.20.15.3.47"/>
        ...
      </substanceAdministration>
    </entryRelationship>
  </act>
</entry>
```

## 4.24 PHCR Treatment given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.55]

This clinical statement represents treatments administered to the subject of the case report, for treatment of reported condition.

1. **SHALL** contain [1..1] **@classCode="SBADM"** *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1919)
2. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1920)
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:1921)
4. **SHALL** contain [1..1] **statusCode** (CONF:1922)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:1923), which if present
  - a. **SHOULD** contain [0..1] **low** (CONF:1924)
6. **SHOULD** contain [0..1] **routeCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **DYNAMIC** (CONF:1925)
7. **SHALL** contain [1..1] **consumable** (CONF:1926), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1927), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1928), which
      1. **SHALL** contain [1..1] **code** (CONF:1929), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:1930)

#### 4.24.1 Anthrax treatment given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.38]

This clinical statement represents the treatments administered to the subject of the case report for the treatment of anthrax.

1. Conforms to PHCR Treatment given Template (templateId: 2.16.840.1.113883.10.20.15.3.55).
2. **SHALL** contain [1..1] **@classCode**="SBADM" *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1337)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1338)
4. **SHALL** contain [1..1] **@negationInd**="false" (CONF:1339)
5. **SHALL** contain [1..1] **statusCode** (CONF:1340)
6. **SHOULD** contain [0..1] **effectiveTime** (CONF:1341), which if present
  - a. **SHOULD** contain [0..1] **low** (CONF:1342)
7. **SHOULD** contain [0..1] **routeCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **DYNAMIC** (CONF:1343)
8. **SHALL** contain [1..1] **consumable** (CONF:1344), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1345), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1346), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3216 Medication Treatment (Anthrax) **DYNAMIC** (CONF:1347), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:1348)



**Figure 62: Anthrax treatment given example**

```
<entryRelationship typeCode="COMP">
  <!-- Anthrax Treatment given -->
  <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.38"/>
    <statusCode code="active"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090309"/>
    </effectiveTime>
    <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="RouteOfAdministration"/>

    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial>
          <code code="5E8K9I004U" codeSystem="2.16.840.1.113883.4.9"
            displayName="Ciprofloxacin">
            <originalText>Ciprofloxacin</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>

  </substanceAdministration>
</entryRelationship>
```

#### 4.24.2 Tuberculosis treatment given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.16]

This clinical statement represents treatments administered to the subject of the case report for the treatment of tuberculosis.

1. Conforms to PHCR Treatment given Template (templateId: 2.16.840.1.113883.10.20.15.3.55).
2. **SHALL** contain [1..1] **@classCode**="SBADM" *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:622)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:623)
4. **SHALL** contain [1..1] **@negationInd**="false" (CONF:624)
5. **SHALL** contain [1..1] **statusCode** (CONF:625)
6. **SHOULD** contain [0..1] **effectiveTime** (CONF:631), which if present
  - a. **SHOULD** contain [0..1] **low** (CONF:634)
7. **SHOULD** contain [0..1] **routeCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **DYNAMIC** (CONF:632)
8. **SHALL** contain [1..1] **consumable** (CONF:626), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:627), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:628), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3218 Medication Treatment (TB) **DYNAMIC** (CONF:629), which

- a. **SHOULD** contain [0..1] **originalText** (CONF:630)

**Figure 63: Tuberculosis treatment given example**

```
<entryRelationship typeCode="COMP">
  <!-- TB Treatment given -->
  <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.16"/>
    <statusCode code="active"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090107"/>
    </effectiveTime>
    <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="RouteOfAdministration"/>
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial>
          <code code="206698" codeSystem="2.16.840.1.113883.6.88"
            displayName="Rifater">
            <originalText>rifampin, isoniazid and pyrazinamide</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entryRelationship>
```

#### 4.24.3 Tularemia treatment given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.47]

This clinical statement represents treatments administered to the subject of the case report for the treatment of tularemia.

1. Conforms to PHCR Treatment given Template (templateId: 2.16.840.1.113883.10.20.15.3.55).
2. **SHALL** contain [1..1] **@classCode**="SBADM" *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1728)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1729)
4. **SHALL** contain [1..1] **@negationInd**="false" (CONF:1730)
5. **SHALL** contain [1..1] **statusCode** (CONF:1731)
6. **SHOULD** contain [0..1] **effectiveTime** (CONF:1732), which if present
  - a. **SHOULD** contain [0..1] **low** (CONF:1733)
7. **SHOULD** contain [0..1] **routeCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **DYNAMIC** (CONF:1734)
8. **SHALL** contain [1..1] **consumable** (CONF:1735), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1736), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1737), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3217 Medication Treatment (Tularemia) **DYNAMIC** (CONF:1738), which

- a. **SHOULD** contain [0..1] **originalText** (CONF:1739)

**Figure 64: Tularemia treatment given example**

```
<entryRelationship typeCode="COMP">
  <!-- Tularemia Treatment given -->
  <substanceAdministration classCode="SBADM"
    moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.15.3.47"/>
    <statusCode code="active"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090309"/>
    </effectiveTime>
    <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="RouteOfAdministration"/>

    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial>
          <code code="Y45QS0730B" codeSystem="2.16.840.1.113883.4.9"
            displayName="STREPTOMYCIN">
            <originalText>Streptomycin</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entryRelationship>
```

## 4.25 PHCR Treatment not given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.56]

This clinical statement represents treatments not administered to the subject of the case report for the treatment of the reported condition. Some workflows may require reporting of typical treatments that were NOT administered.

1. **SHALL** contain [1..1] **@classCode="SBADM"** *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1931)
2. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1932)
3. **SHALL** contain [1..1] **@negationInd="true"** (CONF:1933)
4. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1934)
5. **SHALL** contain [1..1] **consumable** (CONF:1935), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1936), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1937), which
      1. **SHALL** contain [1..1] **code/@code** (CONF:1938), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:1939)

#### 4.25.1 Anthrax treatment not given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.49]

This clinical statement represents treatments not administered to the subject of the case report for the treatment of anthrax. Some workflows may require reporting of typical treatments that were NOT administered.

1. Conforms to PHCR Treatment not given Template (templateId: 2.16.840.1.113883.10.20.15.3.56).
2. **SHALL** contain [1..1] **@classCode**="SBADM" *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1757)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1758)
4. **SHALL** contain [1..1] **@negationInd**="true" (CONF:1759)
5. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1760)
6. **SHALL** contain [1..1] **consumable** (CONF:1761), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1762), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1763), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3216 Medication Treatment (Anthrax) **DYNAMIC** (CONF:1764), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:1765)

#### 4.25.2 Tuberculosis treatment not given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.19]

This clinical statement represents treatments not administered to the subject of the case report for the treatment of tuberculosis. Some workflows may require reporting of typical treatments that were NOT administered.

1. Conforms to PHCR Treatment not given Template (templateId: 2.16.840.1.113883.10.20.15.3.56).
2. **SHALL** contain [1..1] **@classCode**="SBADM" *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:613)
3. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:614)
4. **SHALL** contain [1..1] **@negationInd**="true" (CONF:615)
5. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:616)
6. **SHALL** contain [1..1] **consumable** (CONF:617), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:618), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:619), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3218 Medication Treatment (TB) **DYNAMIC** (CONF:620), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:621)

**Figure 65: Tuberculosis treatment not given example**

```
<entryRelationship typeCode="COMP">
  <!-- TB Treatment not given -->
  <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.15.3.19"/>
    <statusCode code="completed"/>
    <consumable>
      <manufacturedProduct>
        <manufacturedMaterial>
          <code code="8G167061QZ" codeSystem="2.16.840.1.113883.4.9"
            displayName="Ethambutol">
            <originalText>Ethambutol</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entryRelationship>
```

### 4.25.3 Tularemia treatment not given

[substanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.50]

This clinical statement represents treatments not administered to the subject of the case report for the treatment of tularemia. Some workflows may require reporting of typical treatments that were NOT administered.

1. Conforms to PHCR Treatment not given Template (templateId: 2.16.840.1.113883.10.20.15.3.56).
2. **SHALL** contain [1..1] **@classCode="SBADM"** *Substance administration* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1766)
3. **SHALL** contain [1..1] **@moodCode="EVN"** *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1767)
4. **SHALL** contain [1..1] **@negationInd="true"** (CONF:1768)
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1769)
6. **SHALL** contain [1..1] **consumable** (CONF:1770), which
  - a. **SHALL** contain [1..1] **manufacturedProduct** (CONF:1771), which
    - i. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1772), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3217 Medication Treatment (Tularemia) **DYNAMIC** (CONF:1773), which
        - a. **SHOULD** contain [0..1] **originalText** (CONF:1774)

## 4.26 Pregnancy observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.8]

This clinical statement represents current and/or prior pregnancy dates enabling investigators to determine if the subject of the case report was pregnant during the course of a condition.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:451)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:452)
3. **SHALL** contain [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:454)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:455)
5. **SHOULD** contain [0..1] **effectiveTime** (CONF:2018)
6. **SHALL** contain [1..1] **value/@code**="77386006" *Pregnant* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:457)
7. **MAY** contain [0..1] **entryRelationship** (CONF:458) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="REFR" *Refers to* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:459)
  - b. **SHALL** contain [1..1] **Estimated date of delivery** (templateId:2.16.840.1.113883.10.20.15.3.1) (CONF:460)

**Figure 66: Pregnancy observation example**

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.8" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <high value="20061225"/>
    </effectiveTime>
    <value xsi:type="CD" code="77386006" codeSystem="2.16.840.1.113883.6.96"
      displayName="Pregnant"/>
  </observation>
</entry>
```

## 4.27 Race observation

[observation: templateId 2.16.840.1.113883.10.20.15.3.9]

This clinical statement represents the race of the subject of the case report.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:432)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:433)
3. **SHALL** contain [1..1] **code/@code**="32624-9" *Race* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:434)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:435)
5. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.14914 Race **DYNAMIC** (CONF:436)

**Figure 67: Race observation example**

```
<entry typeCode="DRIV">
  <!-- Race observations -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.9" />
    <code code="32624-9" codeSystem="2.16.840.1.113883.6.1" displayName="Race" />
    <statusCode code="completed" />
    <value xsi:type="CD" code="1002-5" codeSystem="2.16.840.1.113883.6.238"
      displayName="AMERICAN INDIAN OR ALASKA NATIVE" />
  </observation>
</entry>
```

## 4.28 Specimen collection procedure

[procedure: templateId 2.16.840.1.113883.10.20.15.3.2]

This clinical statement represents clinical information about the specimen and administrative data such as where (e.g., the name of the lab) the specimen was collected.

1. **SHALL** contain [1..1] **@classCode="PROC" Procedure** (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:691)
2. **SHALL** contain [1..1] **@moodCode="EVN" Event** (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:692)
3. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3204 Non-Laboratory Intervention and Procedure **DYNAMIC** (CONF:693)
4. **SHOULD** contain [0..1] **effectiveTime** (CONF:694)
5. **SHOULD** contain [0..1] **targetSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:695)
6. **SHOULD** contain [0..1] **performer** (CONF:696), which if present
  - a. **SHALL** contain [1..1] **assignedEntity** (CONF:697), which
    - i. **SHALL** contain [1..\*] **id** (CONF:698)
    - ii. **SHALL** contain [1..1] **representedOrganization** (CONF:699), which
      1. **SHALL** contain [1..1] **name** (CONF:700)
7. **SHOULD** contain [0..1] **participant** (CONF:701) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode="PRD" Product** (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:706)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:702), which
    - i. **SHALL** contain [1..1] **@classCode="SPEC" Specimen** (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:707)
    - ii. **SHALL** contain 1..1 **id/@root** which **SHALL** equal **specimenRole/id** (CONF:703).
    - iii. **SHALL** contain [1..1] **playingEntity** (CONF:704), which
      1. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen **DYNAMIC** (CONF:709)

**Figure 68: Specimen collection procedure example**

```
<component>
  <!-- Specimen collection procedure -->
  <procedure classCode="PROC" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.2"/>
    <code code="397394009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Bronchoalveolar lavage"/>
    <effectiveTime value="20081215"/> <!-- Specimen collection date-->
    <!-- Specimen source -->
    <targetSiteCode code="82094008" codeSystem="2.16.840.1.113883.6.96"
      displayName="Lower respiratory tract structure"/>

    <performer>
      <assignedEntity>
        <id root="250a11a0-d079-11dd-ad8b-0800200c9a66"/>
        <!-- ID of Organization collecting specimen -->
        <representedOrganization>
          <name>GHH Outpatient Clinic</name>
          <!-- Name of Organization collecting specimen -->
        </representedOrganization>
      </assignedEntity>
    </performer>

    <participant typeCode="PRD">
      <participantRole classCode="SPEC">
        <id root="d5a9ef50-d05e-11dd-ad8b-0800200c9a66"/>
        <playingEntity>
          <code code="45710003" codeSystem="2.16.840.1.113883.6.96"
            displayName="Sputum"> </code> <!-- Specimen type -->
        </playingEntity>
      </participantRole>
    </participant>

  </procedure>
</component>
```

## 4.29 Susceptibility result

[observation: templateId 2.16.840.1.113883.10.20.15.3.10]

This clinical statement represents the susceptibility of an organism to an antibiotic. Note that participantRole/id shall be set to equal the result observation templateId observation/participant/participantRole/id to show that these susceptibilities are performed on the referenced organism.

1. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:771)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:772)
3. **SHALL** contain [1..1] **code/@code**="18769-0" (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:773)



4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:774)
5. **SHALL** contain [1..1] **participant** (CONF:775) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="SBJ" *Subject* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:776)
  - b. **SHALL** contain [1..1] **participantRole** (CONF:777), which
    - i. **SHALL** contain [1..1] **@classCode**="ISLT" *Isolate* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:778)
    - ii. **SHOULD** contain [0..\*] **id** (CONF:779)
    - iii. **SHOULD** contain [0..1] **playingEntity** (CONF:780), which if present
      1. **SHOULD** contain [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1009 Microorganism **DYNAMIC** (CONF:781)
6. **SHALL** contain [1..\*] **entryRelationship** (CONF:782) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="COMP" *Has component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:926)
  - b. **SHALL** contain [1..1] **observation** (CONF:783), which
    - i. **SHALL** contain [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:784)
    - ii. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:785)
    - iii. **SHALL** contain [1..\*] **id** (CONF:927)
    - iv. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1071 Drug Susceptibility Test Result Name **DYNAMIC** (CONF:786)
    - v. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:787)
    - vi. **SHALL** contain [1..1] **value** (CONF:788)
    - vii. **SHALL** contain [1..1] **interpretationCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC** (CONF:789)

**Figure 69: Susceptibility result example**

```
<entryRelationship typeCode="COMP">
  <!-- Susceptibility result -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.10"/>
    <code code="18769-0" codeSystem="2.16.840.1.113883.6.1"
      displayName="Microbial susceptibility tests"/>
    <statusCode code="completed"/>

    <participant typeCode="SBJ">
      <participantRole classCode="ISLT">
        <id root="63af5c4e-2b78-4d41-bd38-9c3caaf86d64"/>
        <playingEntity>
          <code code="113861009" codeSystem="2.16.840.1.113883.6.96"
            displayName="Mycobacterium tuberculosis"/>
        </playingEntity>
      </participantRole>
    </participant>

    <entryRelationship typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <id nullFlavor="NI"/>
        <code code="424-2" codeSystem="2.16.840.1.113883.6.1"
          displayName="Pyrazinamide MIC"/>
        <statusCode code="completed"/>
        <value xsi:type="PQ" value="0.05" unit="ug/mL"/>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.5.83"
          displayName="Susceptible"/>
      </observation>
    </entryRelationship>

    <entryRelationship typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <id nullFlavor="NI"/>
        <code code="428-3" codeSystem="2.16.840.1.113883.6.1"
          displayName="Rifampin MIC"/>
        <statusCode code="completed"/>
        <value xsi:type="PQ" value="0.04" unit="ug/mL"/>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.5.83"
          displayName="Susceptible"/>
      </observation>
    </entryRelationship>
  </observation>
</entryRelationship>
```

### 4.30 Tuberculosis possible exposure location

[act: templateId 2.16.840.1.113883.10.20.15.3.12]

This clinical statement represents locations where it is possible that an exposure to tuberculosis may have occurred. These are simply locations that have been identified by public health departments as locations that have been associated with higher risk of coming into contact with tuberculosis. The reporter, by asserting that the subject of the case report has frequented any of the locations, is only stating that and is NOT inferring that the patient was definitively exposed at this location.

1. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:746)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:747)
3. **SHALL** contain [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:753), which
  - a. **SHALL** contain [1..1] **qualifier** (CONF:754) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="246090004" *Associated finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:755)
    - ii. **SHALL** contain [1..1] **value/@code**="170464005" *Tuberculosis contact* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:756)
  - b. **SHALL** contain [1..1] **qualifier** (CONF:757) (specialized branch), which
    - i. **SHALL** contain [1..1] **name**="408729009" *Finding context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:765)
    - ii. **SHALL** contain [1..1] **value**="410590009" *Known possible* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:766)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:750)
5. **SHALL** contain [1..\*] **participant** (CONF:758) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:767)
  - b. **SHOULD** contain [0..1] **time** (CONF:860)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:759), which
    - i. **SHALL** contain [1..1] **@classCode**="LOCE" *Located entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:768)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:761)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:762)
    - iv. **SHOULD** contain [0..1] **playingEntity** (CONF:763), which if present
      1. **SHALL** contain [1..1] **@classCode**="PLC" *Place* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:769)
      2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3209 Exposure Location **DYNAMIC** (CONF:764)

**Figure 70: Tuberculosis possible exposure location example**

```
<entry typeCode="DRIV">
  <!-- TB Possible exposure location -->
  <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.12" />
    <code code="413350009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Finding with explicit context">

    <qualifier>
      <name code="246090004" displayName="Associated finding"/>
      <value code="170464005" displayName="Tuberculosis contact"/>
    </qualifier>

    <qualifier>
      <name code="408729009" displayName="Finding context"/>
      <value code="410590009" displayName="Known possible"/>
    </qualifier>
  </code>

  <participant typeCode="LOC">
    <time>
      <low value="2007"/>
      <high value="20090110"/>
    </time>
    <participantRole classCode="LOCE">
      <addr>
        <streetAddressLine>1001 Lone Tree Rd</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
      <telecom value="tel:+1-888-888-8888;ext=9999" />
      <playingEntity classCode="PLC">
        <code code="224864007" codeSystem="2.16.840.1.113883.6.96"
          displayName="College"/>
      </playingEntity>
    </participantRole>
  </participant>

  <participant typeCode="LOC">
    <time>
      <low value="20081101"/>
      <high value="20090110"/>
    </time>
    <participantRole classCode="LOCE">
      <addr>
        <streetAddressLine>1000 Mountain Way</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>99999</postalCode>
        <country>USA</country>
      </addr>
      <telecom value="tel:+1-888-888-8888;ext=9999" />
      <playingEntity classCode="PLC">
        <code code="1348009" codeSystem="2.16.840.1.113883.6.96">
```

```

        displayName="Day care center"/>
    </playingEntity>
</participantRole>
</participant>
</act>
</entry>

```

### 4.31 Tularemia possible exposure location and type

[act: templateId 2.16.840.1.113883.10.20.15.3.43]

This clinical statement represents locations where it is possible that an exposure to tularemia may have occurred. It can also represent the vomite or fomite that may have transmitted tularemia. These are simply locations or vehicles that have been identified by public health departments as associated with higher risk of coming into contact with tularemia. The reporter is NOT inferring that the patient was definitively exposed in this manner. If known, the likely exposure date or date range should be sent. The possible exposure location should capture the address of the location and it may capture the type of location. The type of location is not restricted to any particular value set.

1. **SHALL** contain [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:1617)
2. **SHALL** contain [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:1618)
3. **SHALL** contain [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1619), which
  - a. **SHALL** contain [1..1] **qualifier** (CONF:1620) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="246090004" *Associated finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1621)
    - ii. **SHALL** contain [1..1] **value/@code**="PHC818" *Tularemia exposure* (CodeSystem: 2.16.840.1.114222.4.5.274 PHIN VADS code system) **STATIC** (CONF:1622)
  - b. **SHALL** contain [1..1] **qualifier** (CONF:1623) (specialized branch), which
    - i. **SHALL** contain [1..1] **name/@code**="408729009" *Finding context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1624)
    - ii. **SHALL** contain [1..1] **value/@code**="410590009" *Known possible* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:1625)
4. **SHALL** contain [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:1626)
5. **SHALL** contain [1..\*] **participant** (CONF:1627) (specialized branch), which
  - a. **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1628)
  - b. **SHOULD** contain [0..1] **time** (CONF:1629)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1630), which
    - i. **SHALL** contain [1..1] **@classCode**="LOCE" *Located entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1631)
    - ii. **SHOULD** contain [0..\*] **addr** (CONF:1632)
    - iii. **SHOULD** contain [0..\*] **telecom** (CONF:1633)

- iv. **MAY** contain [0..1] **playingEntity** (CONF:1634), which if present
  - 1. **SHALL** contain [1..1] **@classCode**="PLC" *Place* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1635)
  - 2. **SHALL** contain [1..1] **code** (CONF:1636)
- 6. **MAY** contain [0..\*] **participant** (CONF:1637) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DIR" *Direct target* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1638)
  - b. **SHOULD** contain [0..1] **time** (CONF:1639)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1640), which
    - i. **SHALL** contain [1..1] **@classCode**="EXPR" *Exposed entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1641)
    - ii. **SHALL** contain [1..1] **scopingEntity** (CONF:1642), which
      - 1. **SHALL** contain [1..1] **@classCode**="ANM" *Animal* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1643)
      - 2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1074 *Animal* **DYNAMIC** (CONF:1644)
- 7. **MAY** contain [0..\*] **participant** (CONF:1645) (specialized branch), which if present
  - a. **SHALL** contain [1..1] **@typeCode**="DIR" *Direct target* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:1646)
  - b. **SHOULD** contain [0..1] **time** (CONF:1647)
  - c. **SHALL** contain [1..1] **participantRole** (CONF:1648), which
    - i. **SHALL** contain [1..1] **@classCode**="EXPR" *Exposed entity* (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:1649)
    - ii. **SHALL** contain [1..1] **scopingEntity** (CONF:1650), which
      - 1. **SHALL** contain [1..1] **@classCode**="MAT" *Material* (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:1651)
      - 2. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3211 *Material exposure type* **DYNAMIC** (CONF:1652)

**Figure 71: Tularemia possible exposure location and type example**

```
<entry typeCode="DRIV">
  <!-- Tularemia Possible exposure location and type-->
  <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.43" />
    <code code="413350009" codeSystem="2.16.840.1.113883.6.96"
      displayName="Finding with explicit context">
      <qualifier>
        <name code="246090004" displayName="Associated finding"/>
        <value code="PHC818" displayName="Tularemia exposure"/>
      </qualifier>
      <qualifier>
        <name code="408729009" displayName="Finding context"/>
        <value code="410590009" displayName="Known possible"/>
      </qualifier>
    </code>

    <participant typeCode="LOC">
      <time>
        <low value="20090228"/>
        <high value="20090302"/>
      </time>
      <participantRole classCode="LOCE">
        <addr>
          <streetAddressLine>6666 Home Street</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:+1-888-888-8888;ext=9999" />
        <playingEntity classCode="PLC">
          <code code="224698001" codeSystem="2.16.840.1.113883.6.96"
            displayName="Workshop"/>
        </playingEntity>
      </participantRole>
    </participant>

    <participant typeCode="DIR">
      <time>
        <low value="20090228"/>
        <high value="20090302"/>
      </time>
      <participantRole classCode="EXPR">
        <scopingEntity classCode="MAT">
          <code code="421332005" codeSystem="2.16.840.1.113883.6.96"
            displayName="Animal Hide"/>
        </scopinEntity>
      </participantRole>
    </participant>
  </act>
</entry>
```

## 5 SUPPORTING TEMPLATES

Supporting templates are always used within the context of a clinical statement template. They constrain participants, roles, and entities in the CDA Clinical Statement model.

### 5.1 CCD Location participation

[participant: templateId 2.16.840.1.113883.10.20.1.45]

This clinical statement represents a location.

1. The value for “participant / @typeCode” in a location participation SHALL be “LOC” 2.16.840.1.113883.5.90 ParticipationType STATIC. (CONF: 570).
2. A location participation SHALL contain exactly one participant / participantRole. (CONF: 571).
3. The value for “participant / participantRole / @classCode” in a location participation SHALL be “SDLOC” “Service delivery location” 2.16.840.1.113883.5.110 RoleClass STATIC. (CONF: 572).
4. Participant / participantRole in a location participation MAY contain exactly one participant / participantRole / code. (CONF: 573).
5. The value for “participant / participantRole / code” in a location participation SHOULD be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType 2.16.840.1.113883.5.111 RoleCode DYNAMIC. (CONF: 574).
6. Participant / participantRole in a location participation MAY contain exactly one participant / participantRole / playingEntity. (CONF: 575).
7. The value for “participant / participantRole / playingEntity / @classCode” in a location participation SHALL be “PLC” “Place” 2.16.840.1.113883.5.41 EntityClass STATIC. (CONF: 576).

### 5.2 CCD Product

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.1.53]

This clinical statement represents the details of a medication product.

1. A ManufacturedProduct in a product template SHALL contain exactly one manufacturedProduct / manufacturedMaterial. (CONF: 1038).
2. A manufacturedMaterial in a product template SHALL contain exactly one manufacturedMaterial / code. (CONF: 1039).
3. The value for “manufacturedMaterial / code” in a product template SHOULD be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations , or MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode STATIC 20061017. (CONF: 1040).
4. The value for “manufacturedMaterial / code” in a product template MAY contain a precoordinated product strength, product form, or product concentration (e.g. “metoprolol 25mg tablet”, “amoxicillin 400mg/5mL suspension”). (CONF: 1041).



5. If manufacturedMaterial / code contains a precoordinated unit dose (e.g. “metoprolol 25mg tablet”), then SubstanceAdministration / doseQuantity SHALL be a unitless number that indicates the number of products given per administration. (CONF: 1042).
6. If manufacturedMaterial / code does not contain a precoordinated unit dose (e.g. “metoprolol product”), then SubstanceAdministration / doseQuantity SHALL be a physical quantity that indicates the amount of product given per administration. (CONF: 1043).
7. A manufacturedMaterial in a product template SHALL contain exactly one Material / code / originalText, which represents the generic name of the product. (CONF: 1044).
8. A manufacturedMaterial in a product template MAY contain exactly one Material / name, which represents the brand name of the product. (CONF: 1045).
9. A ManufacturedProduct in a product template MAY contain exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF: 1046).
10. A ManufacturedProduct in a product template MAY contain one or more manufacturedProduct / id, which uniquely represent a particular kind of product. (CONF: 1047).
11. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct SHOULD also contain manufacturedProduct / manufacturerOrganization. (CONF: 1048).

### 5.2.1 Acute hepatitis B immunization product

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.15.3.24]

This clinical statement represents details about the manufactured immunization product.

1. Conforms to CCD Product Template (templateId: 2.16.840.1.113883.10.20.1.53).
2. **SHALL** contain [1..1] **manufacturedMaterial** (CONF:1049), which
  - a. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3219 Vaccine Administered (Hepatitis B) **DYNAMIC** (CONF:1050)

**Figure 72: Acute hepatitis B immunization product example**

```
<consumable>
  <manufacturedProduct>
    <templateId root="2.16.840.1.113883.10.20.15.3.24" />
    <manufacturedMaterial>
      <code code="43" codeSystem="2.16.840.1.113883.6.59"
        displayName="Hep B, adult">
        <originalText>hepatitis B vaccine, adult dosage</originalText>
      </code>
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

## 6 REFERENCES

- HITSP Clinical Document and Message Terminology Component HITSP/C80 - September 12, 2008 Version 0.0.9.
- HITSP CDA and CCD Content Modules Component HITSP/C83 - August 16, 2008 Version 0.0.1.
- HITSP Public Health Case Reporting Interoperability Specification HITSP/IS11 September 26, 2008 Version 0.0.1
- Public Health Reporting and National Notification Definition Statements (09-EC-01 documents)
- HL7 Version 3 Public Health Domain available at: <http://www.hl7.org/v3ballot/html/domains/uvph/uvph.htm> or through [HL7](#).
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: [NHSN Healthcare Associated Infection \(HAI\) Reports](#)
- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through [HL7](#).
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through [HL7](#) or if an HL7 member with the following link: [CDA Release 2 Normative Web Edition](#).
- [LOINC®](#): Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- [SNOMED CT®](#): SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, [www.w3.org/XML](http://www.w3.org/XML).
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: <http://www.jamia.org/cgi/reprint/13/1/30>.
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through [HL7](#) or if an HL7 member with the following link: [Using SNOMED CT in HL7 Version 3](#)

## APPENDIX A — CITED TEMPLATES

This appendix lists templates alphabetically and hierarchically. See Table 3 for templates listed by report type.

### *Alphabetical Lists of Templates by Type*

**Table 4: Document Templates Organized Alphabetically**

Template Title	Template OID
Acute Hepatitis B PHCR CDA R2 report	2.16.840.1.113883.10.20.15.1.2
<a href="#">Anthrax PHCR CDA R2 report</a>	2.16.840.1.113883.10.20.15.1.3
<a href="#">Public Health Case Report CDA R2 template root</a>	2.16.840.1.113883.10.20.15
<a href="#">Tuberculosis PHCR CDA R2 report</a>	2.16.840.1.113883.10.20.15.1.1
<a href="#">Tularemia PHCR CDA R2 report</a>	2.16.840.1.113883.10.20.15.1.4

**Table 5. Section Templates Organized Alphabetically**

Template Title	Template OID
<a href="#">Acute hepatitis B PHCR clinical information section</a>	2.16.840.1.113883.10.20.15.2.12
<a href="#">Acute hepatitis B PHCR immunization section</a>	2.16.840.1.113883.10.20.15.2.9
Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.13
<a href="#">Acute hepatitis B PHCR social history section</a>	2.16.840.1.113883.10.20.15.2.11
<a href="#">Acute hepatitis B PHCR treatment information section</a>	2.16.840.1.113883.10.20.15.2.10
<a href="#">Anthrax PHCR clinical information section</a>	2.16.840.1.113883.10.20.15.2.15
<a href="#">Anthrax PHCR relevant diagnostic tests and/or laboratory data section</a>	2.16.840.1.113883.10.20.15.2.16
<a href="#">Anthrax PHCR social history section</a>	2.16.840.1.113883.10.20.15.2.17
<a href="#">Anthrax PHCR treatment information section</a>	2.16.840.1.113883.10.20.15.2.14
<a href="#">CCD Encounters section</a>	2.16.840.1.113883.10.20.1.3
<a href="#">CCD Immunizations section</a>	2.16.840.1.113883.10.20.1.6
<a href="#">CCD Results section</a>	2.16.840.1.113883.10.20.1.14
<a href="#">CCD Social history section</a>	2.16.840.1.113883.10.20.1.15
<a href="#">PHCR Clinical information section</a>	2.16.840.1.113883.10.20.15.2.1
<a href="#">PHCR Encounters section</a>	2.16.840.1.113883.10.20.15.2.2
<a href="#">PHCR Relevant diagnostic tests and/or laboratory data section</a>	2.16.840.1.113883.10.20.15.2.3
<a href="#">PHCR Social history section</a>	2.16.840.1.113883.10.20.15.2.22

Template Title	Template OID
<a href="#">PHCR Treatment information section</a>	2.16.840.1.113883.10.20.15.2.4
<a href="#">Tuberculosis PHCR clinical information section</a>	2.16.840.1.113883.10.20.15.2.5
<a href="#">Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section</a>	2.16.840.1.113883.10.20.15.2.6
<a href="#">Tuberculosis PHCR social history section</a>	2.16.840.1.113883.10.20.15.2.7
<a href="#">Tuberculosis PHCR treatment information section</a>	2.16.840.1.113883.10.20.15.2.8
<a href="#">Tularemia PHCR clinical information section</a>	2.16.840.1.113883.10.20.15.2.19
<a href="#">Tularemia PHCR relevant diagnostic tests and/or laboratory data section</a>	2.16.840.1.113883.10.20.15.2.21
<a href="#">Tularemia PHCR social history section</a>	2.16.840.1.113883.10.20.15.2.18
<a href="#">Tularemia PHCR treatment information section</a>	2.16.840.1.113883.10.20.15.2.20

**Table 6. Entry Templates Organized Alphabetically**

Template Title	Template OID
<a href="#">Acute hepatitis B actual blood and/or body fluid exposure observation</a>	2.16.840.1.113883.10.20.15.3.26
<a href="#">Acute hepatitis B case observation</a>	2.16.840.1.113883.10.20.15.3.30
<a href="#">Acute hepatitis B immunization activity</a>	2.16.840.1.113883.10.20.15.3.25
<a href="#">Acute hepatitis B possible exposure location and type</a>	2.16.840.1.113883.10.20.15.3.27
<a href="#">Acute hepatitis B result observation</a>	2.16.840.1.113883.10.20.15.3.34
<a href="#">Acute hepatitis B risk associated procedure</a>	2.16.840.1.113883.10.20.15.3.31
<a href="#">Acute hepatitis B signs and symptoms</a>	2.16.840.1.113883.10.20.15.3.22
<a href="#">Acute hepatitis B socio-behavioral boolean risk factor</a>	2.16.840.1.113883.10.20.15.3.28
<a href="#">Acute hepatitis B therapeutic regimen</a>	2.16.840.1.113883.10.20.15.3.23
<a href="#">Anthrax case observation</a>	2.16.840.1.113883.10.20.15.3.36
<a href="#">Anthrax possible exposure location and type</a>	2.16.840.1.113883.10.20.15.3.41
<a href="#">Anthrax result observation</a>	2.16.840.1.113883.10.20.15.3.39
<a href="#">Anthrax result organizer</a>	2.16.840.1.113883.10.20.15.3.40
<a href="#">Anthrax signs and symptoms</a>	2.16.840.1.113883.10.20.15.3.35
<a href="#">Anthrax therapeutic regimen</a>	2.16.840.1.113883.10.20.15.3.37
<a href="#">Anthrax treatment given</a>	2.16.840.1.113883.10.20.15.3.38
<a href="#">Anthrax treatment not given</a>	2.16.840.1.113883.10.20.15.3.49
<a href="#">CCD Encounter activity</a>	2.16.840.1.113883.10.20.1.21
<a href="#">CCD Medication activity</a>	2.16.840.1.113883.10.20.1.24

Template Title	Template OID
<a href="#">CCD Medication series number observation</a>	2.16.840.1.113883.10.20.1.46
<a href="#">CCD Medication status observation</a>	2.16.840.1.113883.10.20.1.47
<a href="#">CCD Problem observation</a>	2.16.840.1.113883.10.20.1.28
<a href="#">CCD Problem status observation</a>	2.16.840.1.113883.10.20.1.50
<a href="#">CCD Result observation</a>	2.16.840.1.113883.10.20.1.31
<a href="#">CCD Result organizer</a>	2.16.840.1.113883.10.20.1.32
<a href="#">CCD Social history observation</a>	2.16.840.1.113883.10.20.1.33
<a href="#">CCD Status observation</a>	2.16.840.1.113883.10.20.1.57
<a href="#">Estimated date of delivery</a>	2.16.840.1.113883.10.20.15.3.1
<a href="#">Geotemporal history observation</a>	2.16.840.1.113883.10.20.15.3.3
<a href="#">HIV status observation</a>	2.16.840.1.113883.10.20.15.3.4
<a href="#">Imaging observation</a>	2.16.840.1.113883.10.20.15.3.5
<a href="#">Job related body fluid exposure risk frequency</a>	2.16.840.1.113883.10.20.15.3.29
<a href="#">Location of lesion observation</a>	2.16.840.1.113883.10.20.15.3.44
<a href="#">Most recent time arrived in USA observation</a>	2.16.840.1.113883.10.20.15.3.6
<a href="#">Occupation observation</a>	2.16.840.1.113883.10.20.15.3.7
<a href="#">Patient condition – alive</a>	2.16.840.1.113883.10.20.15.3.42
<a href="#">Patient condition – deceased</a>	2.16.840.1.113883.10.20.15.3.17
<a href="#">PHCR Case observation</a>	2.16.840.1.113883.10.20.15.3.54
<a href="#">PHCR Result observation</a>	2.16.840.1.113883.10.20.15.3.58
<a href="#">PHCR Result organizer</a>	2.16.840.1.113883.10.20.15.3.59
<a href="#">PHCR Signs and symptoms</a>	2.16.840.1.113883.10.20.15.3.53
<a href="#">PHCR Therapeutic regimen</a>	2.16.840.1.113883.10.20.15.3.57
<a href="#">PHCR Treatment given</a>	2.16.840.1.113883.10.20.15.3.55
<a href="#">PHCR Treatment not given</a>	2.16.840.1.113883.10.20.15.3.56
<a href="#">Pregnancy observation</a>	2.16.840.1.113883.10.20.15.3.8
<a href="#">Race observation</a>	2.16.840.1.113883.10.20.15.3.9
<a href="#">Specimen collection procedure</a>	2.16.840.1.113883.10.20.15.3.2
<a href="#">STD history observation</a>	2.16.840.1.113883.10.20.15.3.33
<a href="#">Susceptibility result</a>	2.16.840.1.113883.10.20.15.3.10
<a href="#">Tuberculosis case observation</a>	2.16.840.1.113883.10.20.15.3.11
<a href="#">Tuberculosis possible exposure location</a>	2.16.840.1.113883.10.20.15.3.12
<a href="#">Tuberculosis result observation</a>	2.16.840.1.113883.10.20.15.3.13

Template Title	Template OID
<a href="#">Tuberculosis result organizer</a>	2.16.840.1.113883.10.20.15.3.21
<a href="#">Tuberculosis signs and symptoms</a>	2.16.840.1.113883.10.20.15.3.14
<a href="#">Tuberculosis socio-behavioral boolean risk factor</a>	2.16.840.1.113883.10.20.15.3.15
<a href="#">Tuberculosis therapeutic regimen</a>	2.16.840.1.113883.10.20.15.3.18
<a href="#">Tuberculosis treatment given</a>	2.16.840.1.113883.10.20.15.3.16
<a href="#">Tuberculosis treatment not given</a>	2.16.840.1.113883.10.20.15.3.19
<a href="#">Tularemia case observation</a>	2.16.840.1.113883.10.20.15.3.46
<a href="#">Tularemia possible exposure location and type</a>	2.16.840.1.113883.10.20.15.3.43
<a href="#">Tularemia result observation</a>	2.16.840.1.113883.10.20.15.3.51
<a href="#">Tularemia result organizer</a>	2.16.840.1.113883.10.20.15.3.52
<a href="#">Tularemia signs and symptoms</a>	2.16.840.1.113883.10.20.15.3.45
<a href="#">Tularemia therapeutic regimen</a>	2.16.840.1.113883.10.20.15.3.48
<a href="#">Tularemia treatment given</a>	2.16.840.1.113883.10.20.15.3.47
<a href="#">Tularemia treatment not given</a>	2.16.840.1.113883.10.20.15.3.50
<a href="#">Viral hepatitis history observation</a>	2.16.840.1.113883.10.20.15.3.32

**Table 7: Supporting Templates Organized Alphabetically**

Template Title	Template OID
<a href="#">Acute hepatitis B immunization product</a>	2.16.840.1.113883.10.20.15.3.24
<a href="#">CCD Location participation</a>	2.16.840.1.113883.10.20.1.45
<a href="#">CCD Product</a>	2.16.840.1.113883.10.20.1.53

## Hierarchical List of Templates

**Table 8: Templates Organized Hierarchically**

Template Title	Template OID
<b>Document Templates</b>	
Public Health Case Report CDA R2 template root	2.16.840.1.113883.10.20.15
Acute Hepatitis B PHCR CDA R2 report	2.16.840.1.113883.10.20.15.1.2
Anthrax PHCR CDA R2 report	2.16.840.1.113883.10.20.15.1.3
Tuberculosis PHCR CDA R2 report	2.16.840.1.113883.10.20.15.1.1
Tularemia PHCR CDA R2 report	2.16.840.1.113883.10.20.15.1.4

Template Title	Template OID
<b>Section Templates</b>	
CCD Encounters section	2.16.840.1.113883.10.20.1.3
PHCR Encounters section	2.16.840.1.113883.10.20.15.2.2
CCD Immunizations section	2.16.840.1.113883.10.20.1.6
Acute hepatitis B PHCR immunization section	2.16.840.1.113883.10.20.15.2.9
CCD Results section	2.16.840.1.113883.10.20.1.14
PHCR Relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.3
Acute hepatitis B PHCR relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.13
Anthrax PHCR relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.16
Tuberculosis PHCR relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.6
Tularemia PHCR relevant diagnostic tests and/or laboratory data section	2.16.840.1.113883.10.20.15.2.21
CCD Social history section	2.16.840.1.113883.10.20.1.15
PHCR Social history section	2.16.840.1.113883.10.20.15.2.22
Acute hepatitis B PHCR social history section	2.16.840.1.113883.10.20.15.2.11
Anthrax PHCR social history section	2.16.840.1.113883.10.20.15.2.17
Tuberculosis PHCR social history section	2.16.840.1.113883.10.20.15.2.7
Tularemia PHCR social history section	2.16.840.1.113883.10.20.15.2.18
PHCR Clinical information section	2.16.840.1.113883.10.20.15.2.1
Acute hepatitis B PHCR clinical information section	2.16.840.1.113883.10.20.15.2.12
Anthrax PHCR clinical information section	2.16.840.1.113883.10.20.15.2.15
Tuberculosis PHCR clinical information section	2.16.840.1.113883.10.20.15.2.5
Tularemia PHCR clinical information section	2.16.840.1.113883.10.20.15.2.19
PHCR Treatment information section	2.16.840.1.113883.10.20.15.2.4
Acute hepatitis B PHCR treatment information section	2.16.840.1.113883.10.20.15.2.10
Anthrax PHCR treatment information section	2.16.840.1.113883.10.20.15.2.14
Tuberculosis PHCR treatment information section	2.16.840.1.113883.10.20.15.2.8
Tularemia PHCR treatment information section	2.16.840.1.113883.10.20.15.2.20

Template Title	Template OID
Clinical Statement Templates	
Acute hepatitis B actual blood and/or body fluid exposure observation	2.16.840.1.113883.10.20.15.3.26
Acute hepatitis B possible exposure location and type	2.16.840.1.113883.10.20.15.3.27
Acute hepatitis B risk associated procedure	2.16.840.1.113883.10.20.15.3.31
Anthrax possible exposure location and type	2.16.840.1.113883.10.20.15.3.41
CCD Encounter activity	2.16.840.1.113883.10.20.1.21
CCD Medication activity	2.16.840.1.113883.10.20.1.24
Acute hepatitis B immunization activity	2.16.840.1.113883.10.20.15.3.25
CCD Medication series number observation	2.16.840.1.113883.10.20.1.46
CCD Problem observation	2.16.840.1.113883.10.20.1.28
PHCR Case observation	2.16.840.1.113883.10.20.15.3.54
Acute hepatitis B case observation	2.16.840.1.113883.10.20.15.3.30
Anthrax case observation	2.16.840.1.113883.10.20.15.3.36
Tuberculosis case observation	2.16.840.1.113883.10.20.15.3.11
Tularemia case observation	2.16.840.1.113883.10.20.15.3.46
Imaging observation	2.16.840.1.113883.10.20.15.3.5
STD history observation	2.16.840.1.113883.10.20.15.3.33
Viral hepatitis history observation	2.16.840.1.113883.10.20.15.3.32
CCD Result observation	2.16.840.1.113883.10.20.1.31
PHCR Result observation	2.16.840.1.113883.10.20.15.3.58
Acute hepatitis B result observation	2.16.840.1.113883.10.20.15.3.34
Anthrax result observation	2.16.840.1.113883.10.20.15.3.39
Tuberculosis result observation	2.16.840.1.113883.10.20.15.3.13
Tularemia result observation	2.16.840.1.113883.10.20.15.3.51
CCD Result organizer	2.16.840.1.113883.10.20.1.32
PHCR Result organizer	2.16.840.1.113883.10.20.15.3.59
Anthrax result organizer	2.16.840.1.113883.10.20.15.3.40
Tuberculosis result organizer	2.16.840.1.113883.10.20.15.3.21
Tularemia result organizer	2.16.840.1.113883.10.20.15.3.52
CCD Social history observation	2.16.840.1.113883.10.20.1.33
Acute hepatitis B socio-behavioral boolean risk factor	2.16.840.1.113883.10.20.15.3.28



Template Title	Template OID
Tuberculosis socio-behavioral boolean risk factor	2.16.840.1.113883.10.20.15.3.15
CCD Status observation	2.16.840.1.113883.10.20.1.57
CCD Medication status observation	2.16.840.1.113883.10.20.1.47
CCD Problem status observation	2.16.840.1.113883.10.20.1.50
Estimated date of delivery	2.16.840.1.113883.10.20.15.3.1
Geotemporal history observation	2.16.840.1.113883.10.20.15.3.3
HIV status observation	2.16.840.1.113883.10.20.15.3.4
Job related body fluid exposure risk frequency	2.16.840.1.113883.10.20.15.3.29
Location of lesion observation	2.16.840.1.113883.10.20.15.3.44
Most recent time arrived in USA observation	2.16.840.1.113883.10.20.15.3.6
Occupation observation	2.16.840.1.113883.10.20.15.3.7
Patient condition – alive	2.16.840.1.113883.10.20.15.3.42
Patient condition – deceased	2.16.840.1.113883.10.20.15.3.17
<b>PHCR Signs and symptoms</b>	2.16.840.1.113883.10.20.15.3.53
Acute hepatitis B signs and symptoms	2.16.840.1.113883.10.20.15.3.22
Anthrax signs and symptoms	2.16.840.1.113883.10.20.15.3.35
Tuberculosis signs and symptoms	2.16.840.1.113883.10.20.15.3.14
Tularemia signs and symptoms	2.16.840.1.113883.10.20.15.3.45
<b>PHCR Therapeutic regimen</b>	2.16.840.1.113883.10.20.15.3.57
Acute hepatitis B therapeutic regimen	2.16.840.1.113883.10.20.15.3.23
Anthrax therapeutic regimen	2.16.840.1.113883.10.20.15.3.37
Tuberculosis therapeutic regimen	2.16.840.1.113883.10.20.15.3.18
Tularemia therapeutic regimen	2.16.840.1.113883.10.20.15.3.48
<b>PHCR Treatment given</b>	2.16.840.1.113883.10.20.15.3.55
Anthrax treatment given	2.16.840.1.113883.10.20.15.3.38
Tuberculosis treatment given	2.16.840.1.113883.10.20.15.3.16
Tularemia treatment given	2.16.840.1.113883.10.20.15.3.47
<b>PHCR Treatment not given</b>	2.16.840.1.113883.10.20.15.3.56
Anthrax treatment not given	2.16.840.1.113883.10.20.15.3.49
Tuberculosis treatment not given	2.16.840.1.113883.10.20.15.3.19
Tularemia treatment not given	2.16.840.1.113883.10.20.15.3.50

Template Title	Template OID
Pregnancy observation	2.16.840.1.113883.10.20.15.3.8
Race observation	2.16.840.1.113883.10.20.15.3.9
Specimen collection procedure	2.16.840.1.113883.10.20.15.3.2
Susceptibility result	2.16.840.1.113883.10.20.15.3.10
Tuberculosis possible exposure location	2.16.840.1.113883.10.20.15.3.12
Tularemia possible exposure location and type	2.16.840.1.113883.10.20.15.3.43
Supporting Templates	
CCD Location participation	2.16.840.1.113883.10.20.1.45
CCD Product	2.16.840.1.113883.10.20.1.53
Acute hepatitis B immunization product	2.16.840.1.113883.10.20.15.3.24

## APPENDIX B — CITED VALUE SETS

All CDA PHCR Value Sets may be accessed in PHIN VADS via [Public Health Case Reporting \(CDA\) Value Sets](#). In addition each PHIN VADS valueSetCode in this table links to the corresponding value set in PHIN VADS. For PHIN VADS questions or problems, please contact PHIN VADS via: [phinvs@cdc.gov](mailto:phinvs@cdc.gov). For further information regarding vocabulary principles, usage and OIDs please see section [1.7.1.2 Vocabularies and Value Sets](#) and [Appendix C —Terminology Principles](#).

**Table 9: Value Set Summary Table**

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
2.16.840.1.114222.4.11.1074	Animal	<a href="#">PHVS Animal CDC</a>	Animal exposure value set is based upon the concepts descending from the SNOMED CT Kingdom Animalia (387961004) hierarchy.
2.16.840.1.114222.4.11.3200	Birth Country	<a href="#">PHVS BirthCountry CDC</a>	Country of Birth value set includes current countries as well as historical countries (eg. USSR). This value set is based upon ISO 3166-1, ISO 3166-3 (retired countries) and FIPS 10-4 (US Territories, Countries that are not found in ISO 3166)
2.16.840.1.114222.4.11.3224	Blood or body fluid exposure event	<a href="#">PHVS BloodOrBodyFluidExposureEvent CDC</a>	Blood or Body Fluid Exposure Event value set has data elements or questions that capture the risk for transmission of disease based on Blood or Body Fluid exposure. This value set is based upon Clinical LOINC.
2.16.840.1.114222.4.11.3225	Blood or body fluid exposure frequency	<a href="#">PHVS BloodOrBodyFluidExposureFrequency</a>	Blood or body fluid exposure frequency value set has qualitative concepts that express the frequency such as frequent and infrequent. This value set is based upon

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
		<a href="#">CDC</a>	SNOMED CT Modifier or Qualifier domain.
2.16.840.1.114222.4.11.3226	Blood or body fluid exposure related procedure	<a href="#">PHVS_BloodorBodyFluidExposureRelatedProcedure_CDC</a>	Procedures involving blood or body fluid exposure often associated certain communicable diseases. This value set is based upon SNOMED CT.
2.16.840.1.114222.4.11.967	Body site	<a href="#">PHVS_BodySite_CDC</a>	Body site value set is based upon the concepts descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.
2.16.840.1.114222.4.11.3210	Contact Type (Hepatitis B)	<a href="#">PHVS_ContactType_HepatitisB</a>	Types of contact that have been identified by public health departments as associated with higher risk of coming into contact with the hepatitis B virus.
2.16.840.1.114222.4.11.876	Detailed Race	<a href="#">PHVS_Race_CDC</a>	Concepts in the race value set include the OMB minimum categories, 5 races, along with a sixth race category, Other race, and a more detailed set of race categories used by the Bureau of Census.
2.16.840.1.114222.4.11.3221	Disease Type (Acute Hepatitis B)	<a href="#">PHVS_DiseaseType_AcuteHepatitisB</a>	Acute hepatitis B disease type value set has problems or disease related to Acute Hepatitis B. This value set is based upon SNOMED CT
2.16.840.1.114222.4.11.3220	Disease Type (Anthrax)	<a href="#">PHVS_DiseaseType_Anthrax</a>	Anthrax disease type value set has problems or disease related to Anthrax. This value set is based upon SNOMED CT

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
2.16.840.1.114222.4.11.3230	Disease Type (Hepatitis)	<a href="#">PHVS_DiseaseType_He patitis</a>	Hepatitis disease type value set has problems or disease related to hepatitis. This value set is based upon SNOMED CT.
2.16.840.1.114222.4.11.3231	Disease Type (STD)	<a href="#">PHVS_DiseaseType_ST D</a>	Sexually Transmitted Disease type value set has problems or disease related to STD. This value set is based upon SNOMED CT.
2.16.840.1.114222.4.11.3222	Disease Type (TB)	<a href="#">PHVS_DiseaseType_TB</a>	Tuberculosis disease type value set has problems or disease related to Tuberculosis. This value set is based upon SNOMED CT.
2.16.840.1.114222.4.11.3223	Disease Type (Tularemia)	<a href="#">PHVS_DiseaseType_Tul aremia</a>	Tularemia disease type value set has problems or disease related to Tuberculosis. This value set is based upon SNOMED CT.
2.16.840.1.114222.4.11.1071	Drug Susceptibility Test Result Name	<a href="#">PHVS_DrugSusceptibili tyTestResultName_CD C</a>	Drug susceptibility tests that are based upon Lab LOINC.
2.16.840.1.114222.4.11.837	Ethnicity group	<a href="#">PHVS_EthnicityGroup CDC</a>	Concepts in the ethnicity group value set include the OMB minimum categories for data on ethnicity (Hispanic or Latino, and Not Hispanic or Latino).
2.16.840.1.114222.4.11.3209	Exposure Location	<a href="#">PHVS_ExposureLocatio n_CDC</a>	Locations that have been identified by public health departments as locations that have been associated with higher risk of coming into contact with infectious

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
			diseases such as tuberculosis and Hepatitis B
2.16.840.1.114222.4.11.3201	Geographical location history	<a href="#">PHVS GeographicLocationHistory CDC</a>	Locations out of US (Birth Country) and jurisdictions within US (states) that are potentially relevant to current condition. This value set is based upon ISO 3166 (Countries) as well as FIPS 5-2 (States).
2.16.840.1.114222.4.11.3232	HIV Status	<a href="#">PHVS HIVStatus CDC</a>	HIV Status value set has concepts that expresses the status of HIV such as HIV negative or HIV positive.
2.16.840.1.114222.4.11.1100	Industry (NAICS)	<a href="#">PHVS Industry NAICS 2007</a>	The North American Industry Classification System (NAICS, pronounced Nakes) was developed as the standard for use by Federal statistical agencies in classifying business establishments for the collection, analysis, and publication of statistical data related to the business economy of the U.S.
2.16.840.1.114222.4.11.1002	Lab Test Result Name	<a href="#">PHVS LabTestName CDC</a>	Lab test result name value set is based upon the concepts from Lab LOINC Class. This includes chemistry, microorganism tests as well as drug susceptibility tests.
2.16.840.1.114222.4.11.3206	Lab Test Result Name (Acute Hepatitis B)	<a href="#">PHVS LabTestResultName AcuteHepatitisB</a>	Acute Hepatitis B lab test result name value set is based upon the Lab LOINC concepts that are defined in the CSTE standardized reporting definition for Acute Hepatitis B.

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
2.16.840.1.114222.4.11.3207	Lab Test Result Name (Anthrax)	<a href="#">PHVS LabTestResultName Anthrax</a>	Anthrax lab test result name value set is based upon the Lab LOINC concepts that are defined in the CSTE standardized reporting definition for Anthrax.
2.16.840.1.114222.4.11.3205	Lab Test Result Name (TB)	<a href="#">PHVS LabTestResultName TB</a>	Tuberculosis lab test result name value set is based upon the Lab LOINC concepts that are defined in the CSTE standardized reporting definition for Tuberculosis.
2.16.840.1.114222.4.11.3208	Lab Test Result Name (Tularemia)	<a href="#">PHVS LabTestResultName Tularemia</a>	Tularemia lab test result name value set is based upon the Lab LOINC concepts that are defined in the CSTE standardized reporting definition for Tularemia.
2.16.840.1.114222.4.11.3227	Location performing blood or body fluid exposure procedure	<a href="#">PHVS LocationPerformingBBFExposureProcedure CDC</a>	Service delivery locations that may perform the procedure on human body involving blood or body fluid. This value set is based upon the HL7 V3 vocabulary.
2.16.840.1.114222.4.11.3211	Material exposure type	<a href="#">PHVS MaterialExposureType CDC</a>	Types of exposure related to material such as suspicious mail and powder, including animal material. This value set is primarily based upon SNOMED CT Material (260769002) hierarchy.
2.16.840.1.114222.4.11.3204	Non-Laboratory Intervention and Procedure	<a href="#">PHVS NonLabInterventionProcedure CDC</a>	This value set includes medical and surgical procedures performed on human body. This is based upon the concepts descending from the SNOMED CT Procedures (7138002) hierarchy. This value set does not include administrative billing procedure or laboratory

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
			procedure.
2.16.840.1.114222.4.11.3216	Medication Treatment (Anthrax)	<a href="#">PHVS_MedicationTreatment Anthrax</a>	Anthrax treatment value set has medication concepts used to treat anthrax. This is based upon the FDA Unique Ingredient Identifier (UNII).
2.16.840.1.114222.4.11.3218	Medication Treatment (TB)	<a href="#">PHVS_MedicationTreatment TB</a>	Tuberculosis treatment value set has medication concepts used to treat tuberculosis. This is primarily based upon the FDA Unique Ingredient Identifier (UNII).
2.16.840.1.114222.4.11.3217	Medication Treatment (Tularemia)	<a href="#">PHVS_MedicationTreatment Tularemia</a>	Tularemia treatment value set has medication concepts used to treat tularemia. This is based upon the FDA Unique Ingredient Identifier (UNII).
2.16.840.1.114222.4.11.1009	Microorganism	<a href="#">PHVS_Microorganism_CDC</a>	Microorganism value set is based upon the concepts descending from the SNOMED CT Microorganism(264395009) hierarchy.
2.16.840.1.114222.4.11.3229	Observation Interpretation (HL7)	<a href="#">PHVS_ObservationInterpretation HL7 V3</a>	Observation interpretation concepts that are based upon HL7 V3 vocabulary.
2.16.840.1.114222.4.11.887	Occupation	<a href="#">PHVS_Occupation_CDC</a>	The 2000 Standard Occupational Classification (SOC) system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data.
2.16.840.1.113883.3.88.12.322	Medication Route FDA	<a href="#">PHVS_MedicationRoute</a>	Route of Administration value set is based upon FDA



Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
1.8.7	Value Set	<a href="#">e FDA</a>	Drug Registration and Listing Database (FDA Orange Book) which are used in FDA structured product and labelling (SPL).
2.16.840.1.114222.4.11.926	Administrative Gender (HL7 V3)	<a href="#">PHVS AdministrativeGender HL7 V3</a>	Administrative Gender based upon HL7 V3 vocabulary. This value set contains only male, female and undifferentiated concepts.
2.16.840.1.114222.4.11.3213	Signs and Symptoms (Acute Hepatitis B)	<a href="#">PHVS SignsSymptomsAcuteHepatitisB</a>	Acute Hepatitis B Signs and Symptoms value set is primarily based upon the SNOMED concepts that are defined in the CSTE standardized reporting definition for Acute Hepatitis B.
2.16.840.1.114222.4.11.3212	Signs and Symptoms (Anthrax)	<a href="#">PHVS SignsSymptomsAnthrax</a>	Anthrax Signs and Symptoms value set is primarily based upon the SNOMED concepts that are defined in the CSTE standardized reporting definition for Anthrax.
2.16.840.1.114222.4.11.3214	Signs and Symptoms (TB)	<a href="#">PHVS SignsSymptomsTB</a>	Tuberculosis Signs and Symptoms value set is primarily based upon the SNOMED concepts that are defined in the CSTE standardized reporting definition for Tuberculosis
2.16.840.1.114222.4.11.3215	Signs and Symptoms (Tularemia)	<a href="#">PHVS SignsSymptomsTularemia</a>	Tularemia Signs and Symptoms value set is primarily based upon the SNOMED concepts that are defined in the CSTE standardized reporting definition for Anthrax
2.16.840.1.114222.4.11.3228	Sociobehavioral risk	<a href="#">PHVS SocioBehavioral</a>	Socio-behavioral risk factor related to infectious

Value Set OID	valueSetName	PHIN VADS valueSetCode	Value Set Description
	factor	<a href="#">RiskFactor_CDC</a>	disease.
2.16.840.1.114222.4.11.946	Specimen	<a href="#">PHVS Specimen_CDC</a>	Specimen value set is based upon the concepts descending from the SNOMED CT Specimen (123038009) hierarchy.
2.16.840.1.114222.4.11.3203	Treatment status	<a href="#">PHVS TreatmentStatus_CDC</a>	Treatment (medication) status value set includes concepts such as active and on hold

## APPENDIX C — TERMINOLOGY PRINCIPLES

### *Introduction*

The high level objectives for vocabulary used by this project included:

- **Consistency with HITSP vocabulary recommendations:** Where HITSP vocabulary recommendations have been developed, they should be used.
- **Consistency within federal agencies:** Discrepancies across federal agencies should be reconciled.
- **Internal consistency within CDC:** Discrepancies across CDC divisions should be reconciled.
- **Consistency across CDA Implementation Guides:** Vocabulary use across CDA Implementation Guides should be consistent within a particular realm.
- **Consistency across HL7 artifacts:** Vocabulary use across HL7 artifacts (e.g., V2 messages and CDA documents) should be consistent within a particular realm.

In some cases, particularly where discrepancies are present between existing legacy applications or where standard codes don't exist for particular CDC/NCPHI requirements, there was a need for an incremental strategy for vocabulary reconciliation for codes, code systems, and value sets.

Based on these objectives and the need for an incremental strategy, the following guidelines show the steps taken in the project to select codes, code systems, and value sets.

### *Code and Code System Selection*

- a) Where there was conflicting precedent within the CDC, the CDC advised on which code system they preferred to use for a particular use case.
- b) Where there was a preferred code system within the CDC that was consistent with HITSP recommendations, existing CDC-cited code systems were used.
- c) Where there was a preferred code system within the CDC that is not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but was outside the scope of this project).
- d) Where there was no established precedent within the CDC, available HITSP recommendations were followed.
- e) Where there was no established precedent within the CDC and no HITSP recommendations, then precedent in prior CDA Implementation Guides were followed.
- f) Where there was no established precedent within the CDC, no HITSP recommendations, and no prior CDA implementation guide precedent:

- i) An attempt was made to map CDC/NCPHI local codes to standard codes (e.g. SNOMED, HL7 V3 vocabularies).
- ii) Where there was no corresponding standard code, the CDC/NCPHI local code was cited. (Submitting local CDC/NCPHI codes to SNOMED is outside the scope of this project).
- g) If post-coordination of SNOMED terms and codes within value sets would be required to capture the CDC/NCPHI concept, the local CDC/NCPHI code was used.

## **Value Set Assignment**

- a) Where there was conflicting precedent within the CDC, the CDC advised on which value set they prefer to use for a particular use case.
- b) Where there was a preferred CDC value set that was consistent with HITSP recommendations, existing CDC value sets were used.
- c) Where there was a preferred CDC value set that was not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but outside the scope of this project).
- d) Where there was no established precedent within the CDC, available HITSP recommendations were followed.
- e) Where there was no established precedent within the CDC and no HITSP recommendations, then precedent in prior CDA implementation guides were followed.
- f) Where there was no established precedent within the CDC, no HITSP recommendations, and no prior CDA implementation guide precedent, new value sets were created, each having a value set OID assigned by the CDC.
- g) Cited value sets are dynamically bound value sets and are included in this CDA CDC/NCPHI PHCR Implementation Guide for convenience in a value set short summary table ([Table 9: Value Set Summary Table](#)) and detailed in a linked spreadsheet ([CDA PHCR IG ValueSets.xls](#)). The latest version of a value set can be obtained from the CDC Public Health Information Network's Vocabulary Access and Distribution System (PHIN VADS) [<http://phinvads.cdc.gov>] by searching on the particular value set OID. Questions about PHIN VADS can be directed to [PHINVS@CDC.GOV](mailto:PHINVS@CDC.GOV).