

Implementation Guide for CDA Release 2

Pertussis Case Report CDA R2

Optional Subtitle



**PROTOTYPE: FOR DISCUSSION
AND DEMONSTRATION USE ONLY
(Consolidated Developer Documentation)**

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Acknowledgments

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Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	December 2010	Dave Carlson	Updated model content and publication format

Chapter 1

INTRODUCTION

Topics:

- [Overview](#)
- [Approach](#)
- [Scope](#)
- [Audience](#)
- [Organization of This Guide](#)
- [Use of Templates](#)
- [Conventions Used in This Guide](#)

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

Approach

Working with specifications generated from formal UML models provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

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 section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement 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 Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

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

Originator Responsibilities

An originator can apply a `templateId` 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. This implementation guide asserts when `templateIds` are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only 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`).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the `templateId` and 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 indicates 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.

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>).
3.

Figure 1: Template name and "conforms to" appearance

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 omit 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
- 2..2 as two must be 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, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

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.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
 - a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
 - a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
 - b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
 - a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

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 The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

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).

Figure 3: CCD conformance statements example

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](#):

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

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.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

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

Chapter

2

DOCUMENT TEMPLATES

Topics:

- [Pertussis Case Report](#)

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Pertussis Case Report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.5]

1. **SHALL** conform to *PHCR Public Health Case Report* template (templateId: 2.16.840.1.113883.10.20.15)
2. Contains exactly one [1..1] **typeId**, where its data type is InfrastructureRootTypeId
3. Contains exactly one [1..1] **id**, where its data type is II
4. **SHALL** contain exactly one [1..1] **code/@code**= "55751-2" *Public Health Case Report* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:546)
5. **SHALL** contain zero or one [0..1] **title** = "Public Health Case Report - Pertussis"
6. Contains exactly one [1..1] **effectiveTime**, where its data type is TS
7. Contains exactly one [1..1] **confidentialityCode**, where its data type is CE
8. Contains at least one [1..*] **recordTarget**, where its type is *Record Target*
9. Contains at least one [1..*] **author**, where its type is *Author*
10. Contains exactly one [1..1] **custodian**, where its type is *Custodian*
11. Contains exactly one [1..1] **component**, where its type is *Component2*
12. **SHOULD** contain zero or one [0..1] **component** (CONF:643, CONF:609), such that
 - a. Contains exactly one [1..1] *Phcr Encounters Section* (templateId: 2.16.840.1.113883.10.20.15.2.2)
13. **SHOULD** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *Pertussis Social History Section* (templateId: 2.16.840.1.113883.10.20.15.2.24)
14. **SHALL** contain exactly one [1..1] **component**, such that
 - a. Contains exactly one [1..1] *Pertussis Clinical Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.25)
15. **SHOULD** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *Pertussis Treatment Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.26)
16. **SHOULD** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *Pertussis Relevant Dx Tests Section* (templateId: 2.16.840.1.113883.10.20.15.2.27)
17. **SHOULD** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *Pertussis Immunizations Section* (templateId: 2.16.840.1.113883.10.20.15.2.28)
18. **SHALL** contain [1..1] recordTarget (CONF:547)
 - [OCL]: self.recordTarget->one(recordTarget : cda::RecordTarget | not recordTarget.ocIsUndefined())
19. RecordTarget **SHALL** contain [1..1] patientRole (CONF:548)
 - [OCL]: self.recordTarget.patientRole->one(patientRole : cda::PatientRole | not patientRole.ocIsUndefined())
20. RecordTarget / PatientRole **SHALL** contain [1..*] id (CONF:549)
 - [OCL]: self.recordTarget.patientRole.id->exists(id : datatypes::II | not id.root.ocIsUndefined() or not id.extension.ocIsUndefined() or not id.nullFlavor.ocIsUndefined())
21. RecordTarget / PatientRole **SHOULD** contain [0..*] addr (CONF:550)
22. RecordTarget / PatientRole **SHOULD** contain [0..*] telecom (CONF:551)
23. RecordTarget / PatientRole **SHOULD** contain [0..1] patient (CONF:552)
24. RecordTarget / PatientRole / Patient **SHOULD** contain [0..*] name (CONF:553)

25. RecordTarget / PatientRole / Patient **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)
26. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] birthTime (CONF:555)
27. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] ethnicGroupCode, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.837 Ethnicity group DYNAMIC (CONF:556)
28. RecordTarget / PatientRole / Patient **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)
29. **SHALL** contain [1..*] author (CONF:1853)
 - [OCL]: self.author->exists(author : cda::Author | not author.ocIsUndefined())
30. Author **SHALL** contain [1..1] time (CONF:560)
 - [OCL]: self.author.time->one(time : datatypes::TS | not time.value.ocIsUndefined() or not time.nullFlavor.ocIsUndefined())
31. Author **SHALL** contain [1..1] assignedAuthor (CONF:561)
 - [OCL]: self.author.assignedAuthor->one(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.ocIsUndefined())
32. Author / AssignedAuthor **SHALL** contain [1..*] id (CONF:562)
 - [OCL]: self.author.assignedAuthor.id->exists(id : datatypes::II | not id.root.ocIsUndefined() or not id.extension.ocIsUndefined() or not id.nullFlavor.ocIsUndefined())
33. Author / AssignedAuthor **SHALL** contain [1..1] addr (CONF:562)
 - [OCL]: self.author.assignedAuthor.addr->one(addr : datatypes::AD | not addr.ocIsUndefined())
34. Author / AssignedAuthor **SHALL** contain [1..1] telecom (CONF:564)
 - [OCL]: self.author.assignedAuthor.telecom->one(tel : datatypes::TEL | not tel.ocIsUndefined())
35. Author / AssignedAuthor **SHALL** contain [1..1] assignedPerson/name (CONF:565)
 - [OCL]: self.author.assignedAuthor.assignedPerson->one(assignedPerson : cda::Person | not assignedPerson.ocIsUndefined()) and self.author.assignedAuthor.assignedPerson.name->one(name : datatypes::PN | not name.ocIsUndefined())
36. The custodian of a public health case report **SHALL** be the reporting organization. (CONF:1616)
37. **SHALL** contain [1..1] legalAuthenticator (CONF:1854)
 - [OCL]: self.legalAuthenticator->one(legalAuthenticator : cda::LegalAuthenticator | not legalAuthenticator.ocIsUndefined())
38. LegalAuthenticator **SHALL** contain [1..1] time (CONF:1855)
 - [OCL]: self.legalAuthenticator.time->one(time : datatypes::TS | not time.value.ocIsUndefined() or not time.nullFlavor.ocIsUndefined())
39. LegalAuthenticator **SHALL** contain [1..1] assignedEntity (CONF:1856)
 - [OCL]: self.legalAuthenticator.assignedEntity->one(assignedEntity : cda::AssignedEntity | not assignedEntity.ocIsUndefined())
40. LegalAuthenticator / AssignedEntity **SHALL** contain [1..*] id (CONF:1857)
 - [OCL]: self.legalAuthenticator.assignedEntity.id->exists(id : datatypes::II | not id.root.ocIsUndefined() or not id.extension.ocIsUndefined() or not id.nullFlavor.ocIsUndefined())
41. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] addr (CONF:1857)
 - [OCL]: self.legalAuthenticator.assignedEntity.addr->one(addr : datatypes::AD | not addr.ocIsUndefined())
42. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] telecom (CONF:1859)
43. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] assignedPerson/name (CONF:1860)
 - [OCL]: self.legalAuthenticator.assignedEntity.assignedPerson->one(assignedPerson : cda::Person | not assignedPerson.ocIsUndefined())

```
and self.legalAuthenticator.assignedEntity.assignedPerson.name-  
>one(name : datatypes::PN | not name.ocIsUndefined())
```

- 44.** 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)

Pertussis Case Report example

Chapter

3

SECTION TEMPLATES

Topics:

- *Pertussis Clinical Information Section*
- *Pertussis Immunizations Section*
- *Pertussis Relevant Dx Tests Section*
- *Pertussis Social History Section*
- *Pertussis Treatment Information Section*

Pertussis Clinical Information Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.25]

1. **SHALL** conform to [PHCR Phcr Clinical Information Section](#) template (templateId: 2.16.840.1.113883.10.20.15.2.1)
2. **SHALL** contain exactly one [1..1] **code/@code**="55752-0" *Clinical Information* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:540)
3. **SHALL** contain exactly one [1..1] **title** = "Clinical Information" (CONF:541)
4. **SHALL** contain exactly one [1..1] **text** (CONF:542)
5. **SHOULD** contain zero or more [0..*] **entry**, such that
 - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
 - b. Contains exactly one [1..1] [Phcr Relevant Medical Condition History Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.62)
6. **MAY** contain zero or one [0..1] **entry** (CONF:1912, CONF:1913, CONF:1914), such that
 - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
 - b. Contains exactly one [1..1] [Patient Condition Alive Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.42)
7. **MAY** contain zero or one [0..1] **entry** (CONF:1915, CONF:1916, CONF:1917), such that
 - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
 - b. Contains exactly one [1..1] [Patient Condition Deceased Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.17)
8. **SHALL** contain exactly one [1..1] **entry**, such that
 - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
 - b. Contains exactly one [1..1] [Pertussis Case Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.65)
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:1918)
 - [OCL]: self.getObservations()->exists(obs3 : cda::Observation | obs3.ocIsKindOf(phcr::PatientConditionAliveObservation) and not self.getObservations()->exists(obs4 : cda::Observation | obs4.ocIsKindOf(phcr::PatientConditionDeceasedObservation))) or self.getObservations()->exists(obs1 : cda::Observation | obs1.ocIsKindOf(phcr::PatientConditionDeceasedObservation) and not self.getObservations()->exists(obs2 : cda::Observation | obs2.ocIsKindOf(phcr::PatientConditionAliveObservation))) or self.getObservations()->forall(obs : cda::Observation | not obs.ocIsKindOf(phcr::PatientConditionAliveObservation) and not obs.ocIsKindOf(phcr::PatientConditionDeceasedObservation))

Pertussis Clinical Information Section example

Pertussis Immunizations Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.28]

1. **SHALL** conform to [CCD Immunizations Section](#) template (templateId: 2.16.840.1.113883.10.20.1.6)
2. **SHALL** contain exactly one [1..1] **code/@code**="11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-377, CONF-378)
3. **SHALL** contain exactly one [1..1] **title** (CONF-379)
4. **SHALL** contain exactly one [1..1] **text** (CONF-376)

5. **SHOULD** contain zero or more [0..*] **entry** (CONF-298), such that
 - a. Contains exactly one [1..1] *Supply Activity* (templateId: 2.16.840.1.113883.10.20.1.34)
6. **SHOULD** contain zero or more [0..*] **entry**, such that
 - a. Contains exactly one [1..1] *Pertussis Immunization Activity* (templateId: 2.16.840.1.113883.10.20.15.3.72)
7. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'. (CONF-380)
 - UNIMPLEMENTABLE
8. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity.
 - ```
[OCL]: self.getSubstanceAdministrations()->exists(activity : cda::SubstanceAdministration | activity.ocIsKindOf(ccd::MedicationActivity)) or self.getSupplies()->exists(activity : cda::Supply | activity.ocIsKindOf(ccd::SupplyActivity))
```
9. **SHALL** satisfy: The absence of known medications is explicitly asserted.
  - UNIMPLEMENTABLE

#### Pertussis Immunizations Section example

## Pertussis Relevant Dx Tests Section

---

[Section: templateId 2.16.840.1.113883.10.20.15.2.27]

1. **SHALL** conform to *CCD Results Section* template (templateId: 2.16.840.1.113883.10.20.1.14)
2. **SHALL** conform to *PHCR Phcr Relevant Dx Tests Section* template (templateId: 2.16.840.1.113883.10.20.15.2.3)
3. **SHALL** contain exactly one [1..1] **code/@code**="30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-389)
4. **SHALL** contain exactly one [1..1] **title**="Relevant diagnostic tests and/or laboratory data" (CONF-391)
5. **SHALL** contain exactly one [1..1] **text** (CONF-388, CONF-737)
6. **MAY** contain zero or more [0..\*] **entry** (CONF-2014, CONF-2015, CONF-2016), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Imaging Observation* (templateId: 2.16.840.1.113883.10.20.15.3.5)
7. **SHOULD** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Pertussis Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.71)
8. **MAY** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Pertussis Result Organizer* (templateId: 2.16.840.1.113883.10.20.15.3.70)
9. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
  - UNIMPLEMENTABLE

#### Pertussis Relevant Dx Tests Section example

## Pertussis Social History Section

---

[Section: templateId 2.16.840.1.113883.10.20.15.2.24]

1. **SHALL** conform to *CCD Social History Section* template (templateId: 2.16.840.1.113883.10.20.1.15)
2. **SHALL** conform to *PHCR Phcr Social History Section* template (templateId: 2.16.840.1.113883.10.20.15.2.22)
3. **SHALL** contain exactly one [1..1] **code**/**@code**="29762-2" *Social History* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:1894)
4. **SHALL** contain exactly one [1..1] **title** = "Social History" (CONF:1895)
5. **SHALL** contain exactly one [1..1] **text** (CONF:1896)
6. **SHOULD** contain zero or more [0..\*] **entry**, such that
  - a. Contains exactly one [1..1] *Social History Observation* (templateId: 2.16.840.1.113883.10.20.1.33)
7. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1897, CONF:1898, CONF:1899), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Geotemporal History Observation* (templateId: 2.16.840.1.113883.10.20.15.3.3)
8. **SHOULD** contain zero or one [0..1] **entry** (CONF:1900, CONF:1901, CONF:1902), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Most Recent Time Arrived In USA Observation* (templateId: 2.16.840.1.113883.10.20.15.3.6)
9. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1903, CONF:1904, CONF:1905), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Race Observation* (templateId: 2.16.840.1.113883.10.20.15.3.9)
10. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1906, CONF:1907, CONF:1908), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Occupation Observation* (templateId: 2.16.840.1.113883.10.20.15.3.7)
11. **MAY** contain zero or more [0..\*] **entry** (CONF:1909, CONF:1910, CONF:1911), such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Pregnancy Observation* (templateId: 2.16.840.1.113883.10.20.15.3.8)
12. **MAY** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Pertussis Possible Exposure Location Act* (templateId: 2.16.840.1.113883.10.20.15.3.63)
13. **MAY** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Pertussis Possible Case Contact Location Act* (templateId: 2.16.840.1.113883.10.20.15.3.64)
14. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'social history'. (CONF-236)
  - UNIMPLEMENTABLE
15. Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations (CONF-250)
  - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.maritalStatusCode.hasContent())->isEmpty()
16. Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations (CONF-251)
  - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.religiousAffiliationCode.hasContent())->isEmpty()
17. A patients race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations (CONF-252)
  - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.raceCode.hasContent())->isEmpty()

18. The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race) (CONF-253)

- [OCL]: self.getClinicalDocument().recordTarget->forAll(r | r.patientRole.patient.raceCode.codeSystem = '2.16.840.1.113883.5.104' )

19. A patients ethnicity **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information **MAY** be represented as social history observations. (CONF-254)

- [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.ethnicGroupCode.hasContent() )->isEmpty()

20. The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity). (CONF-255)

- [OCL]: self.getClinicalDocument().recordTarget->forAll(r | r.patientRole.patient.ethnicGroupCode.codeSystem = '2.16.840.1.113883.5.50' )

### Pertussis Social History Section example

## Pertussis Treatment Information Section

---

[Section: templateId 2.16.840.1.113883.10.20.15.2.26]

1. **SHALL** conform to *PHCR Phcr Treatment Information Section* template (templateId: 2.16.840.1.113883.10.20.15.2.4)
2. **SHALL** contain exactly one [1..1] **code/@code="55753-8" Treatment Information** (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:663)
3. **SHALL** contain exactly one [1..1] **title = "Treatment Information"** (CONF:664)
4. **SHALL** contain exactly one [1..1] **text** (CONF:665)
5. **SHALL** contain exactly one [1..1] **entry**, such that
  - a. Contains **@typeCode="DRIV" DRIV** (is derived from)
  - b. Contains exactly one [1..1] *Pertussis Therapeutic Regimen Act* (templateId: 2.16.840.1.113883.10.20.15.3.67)

### Pertussis Treatment Information Section example



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# Chapter

# 4

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## CLINICAL STATEMENT TEMPLATES

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### Topics:

- [\*Pertussis Case Observation\*](#)
- [\*Pertussis Immunization Activity\*](#)
- [\*Pertussis Possible Case Contact Location Act\*](#)
- [\*Pertussis Possible Exposure Location Act\*](#)
- [\*Pertussis Result Observation\*](#)
- [\*Pertussis Result Organizer\*](#)
- [\*Pertussis Signs And Symptoms Observation\*](#)
- [\*Pertussis Therapeutic Regimen Act\*](#)
- [\*Pertussis Treatment Given Substance Administration\*](#)
- [\*Pertussis Treatment Not Given Substance Administration\*](#)

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

## Pertussis Case Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.65]

1. **SHALL** conform to [CCD Problem Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.28)
2. **SHALL** conform to [PHCR Case Observation](#) template (templateId: 2.16.840.1.113883.10.20.15.3.54)
3. **SHALL** contain exactly one [1..1] **@classCode**= "OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1868)
4. **SHALL** contain exactly one [1..1] **@moodCode**= "EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1869)
5. **MAY** contain zero or more [0..\*] **id** (CONF:1870)
6. **SHALL** contain exactly one [1..1] **code/@code**= "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (CONF:1871)
7. **SHALL** contain exactly one [1..1] **statusCode/@code**= "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1872)
8. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:1873)
9. **SHALL** contain exactly one [1..1] **value/@code**= "27836007" *Pertussis* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT), where its data type is CD
10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-162), such that
  - a. Contains **@typeCode**= "REFR" *REFR (refers to)*
  - b. Contains exactly one [1..1] [Problem Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.50)
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-165), such that
  - a. Contains **@typeCode**= "REFR" *REFR (refers to)*
  - b. Contains exactly one [1..1] [Problem Health Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.51)
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160), such that
  - a. Contains **@typeCode**= "SUBJ" *SUBJ (has subject)*
  - b. Contains exactly one [1..1] [Age Observation](#) (templateId: 2.16.840.1.113883.10.20.1.38)
13. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:1884, CONF:1885, CONF:1886), such that
  - a. Contains **@typeCode**= "REFR" *REFR (refers to)*
  - b. Contains exactly one [1..1] [CCD Problem Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.50)
14. **SHOULD** contain zero or more [0..\*] **entryRelationship**, such that
  - a. Contains exactly one [1..1] [Pertussis Signs And Symptoms Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.66)
15. **SHALL** contain one or more sources of information. (CONF-161)
  - [OCL]: not self.informant->isEmpty()  
 or not self.getSection().informant->isEmpty()  
 or not self.getClinicalDocument().informant->isEmpty()  
 or self.reference->exists(ref : cda::Reference | ref.typeCode =  
 vocab::x\_ActRelationshipExternalReference::XCRPT)  
 or (self.entryRelationship->exists(rel : cda::EntryRelationship |  
 rel.typeCode = vocab::x\_ActRelationshipEntryRelationship::REFR  
 and rel.observation.code.code = '48766-0'))
16. **MAY** contain exactly one Patient Awareness (CONF-180)
  - [OCL]: self.participant->one(partic : cda::Participant2 |  
 partic.oclIsKindOf(ccd::PatientAwareness))



17. **SHOULD** contain [0..1] `effectiveTime/low` (CONF:1873)

- `[OCL]: self.effectiveTime->exists(time : datatypes::IVL_TS | not time.low.ocIsUndefined())`

18. **SHOULD** contain [0..1] `author` (CONF:1875)

- `[OCL]: self.author->exists(author : cda::Author | not author.ocIsUndefined())`

19. Author **SHALL** contain [1..1] `time` (CONF:1876)

20. Author **SHALL** contain [1..1] `assignedAuthor` (CONF:1877)

- `[OCL]: self.author.assignedAuthor->exists(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.ocIsUndefined())`

21. Author / AssignedAuthor **SHALL** contain [1..\*] `id` (CONF:1878)

22. Author / AssignedAuthor **MAY** contain [0..\*] `addr` (CONF:1879)

23. Author / AssignedAuthor **MAY** contain [0..\*] `telecom` (CONF:1880)

24. Author / AssignedAuthor **MAY** contain [0..1] `assignedPerson` (CONF:1881)

25. Author / AssignedAuthor / Person **MAY** contain [0..1] `name` (CONF:1882)

26. Author / AssignedAuthor **MAY** contain [0..1] `representedOrganization` (CONF:1883)

### Pertussis Case Observation example

## Pertussis Immunization Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.72]

1. **SHALL** conform to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)

2. Contains exactly one [1..1] `@classCode="SBADM"` (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass), where its data type is ActClass

3. **SHALL** contain exactly one [1..1] `@moodCode`

4. **SHALL** contain at least one [1..\*] `id` (CONF-306)

5. **SHOULD** contain exactly one [1..1] `statusCode` (CONF-307)

6. **SHOULD** contain at least one [1..\*] `effectiveTime` (CONF-308)

- Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.

7. **SHOULD** contain exactly one [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration) (CONF-309, CONF-310)

8. **SHOULD** contain zero or one [0..1] `doseQuantity`

9. **SHOULD** contain zero or one [0..1] `rateQuantity`

10. **MAY** contain exactly one [1..1] `maxDoseQuantity` (CONF-312)

- represents a maximum dose limit

11. Contains exactly one [1..1] `consumable`, where its type is [Consumable](#)

12. **MAY** contain exactly one [1..1] `entryRelationship` (CONF-338, CONF-339), such that

- Contains `@typeCode="SUBJ"` *SUBJ (has subject)*
- Contains exactly one [1..1] [Medication Series Number Observation](#) (templateId: 2.16.840.1.113883.10.20.1.46)

13. **MAY** contain exactly one [1..1] `entryRelationship` (CONF-350), such that

- Contains exactly one [1..1] [Medication Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.47)

14. **MAY** contain at least one [1..\*] `entryRelationship` (CONF-330, CONF-333), such that

- Contains `@typeCode="SUBJ"` *SUBJ (has subject)*
- Contains exactly one [1..1] [Patient Instruction](#) (templateId: 2.16.840.1.113883.10.20.1.49)

15. **MAY** contain at least one [1..\*] `performer` (CONF-313), such that

- Indicates the person administering a substance.
- 16. MAY** contain at least one [1..\*] **entryRelationship** (CONF-348, CONF-349), such that
- a. Contains **@typeCode="CAUS"** *CAUS (is etiology for)*
  - b. Contains exactly one [1..1] **Reaction Observation** (templateId: 2.16.840.1.113883.10.20.1.54)
- 17. MAY** contain at least one [1..\*] **participant** (CONF-368), such that
- a. Contains exactly one [1..1] **Product Instance** (templateId: 2.16.840.1.113883.10.20.1.52)
- 18. SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
- [OCL]: `self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
- 19. SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
- [OCL]: `not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()`
- 20. MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
- [OCL]: `self.getClinicalDocument().authorization->size() > 0 and self.getClinicalDocument().authorization.consent->size() > 0`
- 21. SHALL** satisfy: Contains one or more sources of information. (CONF-315)
- [OCL]: `not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`
- 22. MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
- Indicates that the medication is administered only when the associated (coded or free text) criteria are met.
  - [OCL]: `self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.ocIsUndefined())`
- 23. MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
- The target of the relationship represents the indication for the activity.
  - [OCL]: `self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`
- 24. SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(ccd::ProblemObservation)))`
- 25. SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
- [OCL]: `self.consumable.manufacturedProduct.ocIsKindOf(ccd::Product)`

### Pertussis Immunization Activity example

## Pertussis Possible Case Contact Location Act

---

[Act: templateId 2.16.840.1.113883.10.20.15.3.64]

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
5. **SHALL** contain [1..\*] participant, which **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC**

**Pertussis Possible Case Contact Location Act example**

## Pertussis Possible Exposure Location Act

---

[Act: templateId 2.16.840.1.113883.10.20.15.3.63]

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
3. **SHALL** contain exactly one [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
5. **SHALL** contain [1..\*] participant, which **SHALL** contain [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC**

**Pertussis Possible Exposure Location Act example**

## Pertussis Result Observation

---

[Observation: templateId 2.16.840.1.113883.10.20.15.3.71]

1. **SHALL** conform to *CCD Result Observation* template (templateId: 2.16.840.1.113883.10.20.1.31)
2. **SHALL** conform to *PHCR Result Observation* template (templateId: 2.16.840.1.113883.10.20.15.3.58)
3. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1967)
4. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-408)
5. **SHALL** contain at least one [1..\*] **id** (CONF-409)
6. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.4184 *Lab Test Name (Pertussis)* **DYNAMIC**
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1971)
8. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF-411)
  - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).

9. **SHALL** contain exactly one [1..1] **value** (CONF-416)
10. **SHOULD** contain zero or more [0..\*] **interpretationCode** (CONF-418)
  - 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.
11. **MAY** contain zero or one [0..1] **methodCode** (CONF-414)
  - Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
12. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:1990), such that
  - a. Contains **@typeCode="REFR"** *REFR (refers to)*
  - b. Contains exactly one [1..1] *Specimen Collection Procedure* (templateId: 2.16.840.1.113883.10.20.15.3.2)
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:1993), such that
  - a. Contains **@typeCode="COMP"** *COMP (has component)*
  - b. Contains exactly one [1..1] *Susceptibility Result* (templateId: 2.16.840.1.113883.10.20.15.3.10)
14. The value for 'code' **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-413)
  - ```
[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor
      self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem
      = '2.16.840.1.113883.6.12'
```
15. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
 - UNIMPLEMENTABLE
16. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
 - UNIMPLEMENTABLE
17. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
 - ```
[OCL]: not self.referenceRange->isEmpty()
```
18. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
  - ```
[OCL]: self.referenceRange->forall(range : cda::ReferenceRange |
      range.observationRange.code.code.ocIsUndefined())
```
19. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
 - ```
[OCL]: not self.informant->isEmpty()
 or not self.getSection().informant->isEmpty()
 or not self.getClinicalDocument().informant->isEmpty()
 or self.reference->exists(ref : cda::Reference | ref.typeCode =
 vocab::x_ActRelationshipExternalReference::XCRPT)
 or (self.entryRelationship->exists(rel : cda::EntryRelationship |
 rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
 and rel.observation.code.code = '48766-0'))
```

#### Pertussis Result Observation example

## Pertussis Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.70]

1. **SHALL** conform to *CCD Result Organizer* template (templateId: 2.16.840.1.113883.10.20.1.32)
2. **SHALL** conform to *PHCR Result Organizer* template (templateId: 2.16.840.1.113883.10.20.15.3.59)

3. **SHALL** contain exactly one [1..1] **@classCode**="BATTERY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1996)
4. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:394, CONF:1997)
5. **SHALL** contain at least one [1..\*] **id** (CONF:395, CONF:1998)
6. **SHALL** contain exactly one [1..1] **code**
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:2000)
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:2001)
9. **SHOULD** contain at least one [1..\*] **specimen** (CONF:399), such that
  - Should be included if the specimen isn't inherent in code value.
10. **MAY** contain zero or one [0..1] **component** (CONF:2009, CONF:2010), such that
  - a. Contains exactly one [1..1] *Specimen Collection Procedure* (templateId: 2.16.840.1.113883.10.20.15.3.2)
11. **SHALL** contain at least one [1..\*] **component**, such that
  - a. Contains exactly one [1..1] *Pertussis Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.71)
12. The value for '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:398)
  - ```
[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor
      self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem
      = '2.16.840.1.113883.6.12' xor self.code.codeSystem =
      '2.16.840.1.113883.1.11.20.16'
```
13. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF:400)
 - UNIMPLEMENTABLE
14. specimen / specimenRole / id **SHOULD** be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF:401)
 - UNIMPLEMENTABLE
15. **SHALL** satisfy: Contains one or more component (CONF:402)
 - ```
[OCL]: not self.component->isEmpty()
```
16. The target of one or more result 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 code or if there is a need to further specialize the code value. (CONF:403)
  - UNIMPLEMENTABLE
17. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF:404)
  - UNIMPLEMENTABLE
18. **SHALL** satisfy: Contains one or more sources of information. (CONF:406)
  - ```
[OCL]: not self.informant->isEmpty()
      or not self.getSection().informant->isEmpty()
      or not self.getClinicalDocument().informant->isEmpty()
      or self.reference->exists(ref : cda::Reference | ref.typeCode =
      vocab::x_ActRelationshipExternalReference::XCRPT)
```

Pertussis Result Organizer example

Pertussis Signs And Symptoms Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.66]

1. **SHALL** conform to *PHCR Signs And Symptoms Observation* template (templateId: 2.16.840.1.113883.10.20.15.3.53)
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1861)
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1862)
4. **SHALL** contain exactly one [1..1] **@negationInd** (CONF:1863)
5. **SHALL** contain exactly one [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (CONF:1864)
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1865)
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:1866)
8. **SHALL** contain exactly one [1..1] **value**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.6016 *Signs and Symptoms (Pertussis) DYNAMIC*, where its data type is CD
9. PHCR Case Observation **SHOULD** contain zero or more [0..*] **entryRelationship** (CONF:1887, CONF:1888, CONF:1890), such that Contains **@typeCode**="MFST" MFST (is manifestation of), such that Contains **@inversionInd**="true", and Contains exactly one [1..1] Signs And Symptoms Observation (templateId: 2.16.840.1.113883.10.20.15.3.53) (CONF:1889)

Pertussis Signs And Symptoms Observation example

Pertussis Therapeutic Regimen Act

[Act: templateId 2.16.840.1.113883.10.20.15.3.67]

1. **SHALL** conform to *PHCR Therapeutic Regimen Act* template (templateId: 2.16.840.1.113883.10.20.15.3.57)
2. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1940)
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1941)
4. **SHALL** contain exactly one [1..1] **@negationInd** (CONF:1942)
5. **SHALL** contain exactly one [1..1] **code/@code**="133877004" *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:1943)
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1944)
7. **SHOULD** contain zero or more [0..*] **entryRelationship**, such that
 - a. Contains **@typeCode**="COMP" *COMP (has component)*
 - b. Contains exactly one [1..1] *Pertussis Treatment Given Substance Administration* (templateId: 2.16.840.1.113883.10.20.15.3.68)
8. **MAY** contain zero or more [0..*] **entryRelationship**, such that
 - a. Contains **@typeCode**="COMP" *COMP (has component)*
 - b. Contains exactly one [1..1] *Pertussis Treatment Not Given Substance Administration* (templateId: 2.16.840.1.113883.10.20.15.3.69)
9. **SHALL**

Pertussis Therapeutic Regimen Act example

Pertussis Treatment Given Substance Administration

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.68]

1. **SHALL** conform to *PHCR Treatment Given Substance Administration* template (templateId: 2.16.840.1.113883.10.20.15.3.55)
2. **SHALL** contain exactly one [1..1] **@classCode**="SBADM" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1919)
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1920)
4. **SHALL** contain exactly one [1..1] **@negationInd** (CONF:1921)
5. **SHALL** contain exactly one [1..1] **statusCode** (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1922)
6. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:1923)
7. **SHALL** contain zero or one [0..1] **routeCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 *Medication Route FDA DYNAMIC* (CONF:1925)
8. Contains exactly one [1..1] **consumable**, where its type is *Consumable*
9. **SHOULD** satisfy: Should contain [0..1] low (CONF:1924)
10. **SHALL** satisfy: Shall contain consumable (CONF:1926)
11. **SHALL** contain exactly one [1..1] **@negationInd**="false" (CONF:1921)
 - [OCL]: `self.negationInd=false`
12. **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3120 Antibiotic Received (Pertussis)

Pertussis Treatment Given Substance Administration example

Pertussis Treatment Not Given Substance Administration

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.15.3.69]

1. **SHALL** conform to *PHCR Treatment Not Given Substance Administration* template (templateId: 2.16.840.1.113883.10.20.15.3.56)
2. **SHALL** contain exactly one [1..1] **@classCode**="SBADM" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1931)
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1932)
4. **SHALL** contain exactly one [1..1] **@negationInd** (CONF:1933)
5. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1934)
6. Contains exactly one [1..1] **consumable**, where its type is *Consumable*
7. **SHALL** satisfy: Shall contain consumable (CONF:1935)
8. **SHALL** contain exactly one [1..1] **@negationInd**="true" (CONF:1933)
 - [OCL]: `self.negationInd=true`
9. **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3120 Antibiotic Received (Pertussis)

Pertussis Treatment Not Given Substance Administration example

Chapter

5

OTHER CLASSES

Topics:

- [Pertussis Immunization Product](#)

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

Pertussis Immunization Product

[ManufacturedProduct: templateId 2.16.840.1.113883.10.20.15.3.73]

1. **SHALL** conform to *CCD Product* template (templateId: 2.16.840.1.113883.10.20.1.53)
2. **MAY** contain at least one [1..*] **id** (CONF-366)
 - uniquely represents a particular kind of product
3. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
 - [OCL]: `not self.manufacturedMaterial.ocIsUndefined()`
4. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
 - [OCL]: `not self.manufacturedMaterial.code.ocIsUndefined()`
5. 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 immunizations¹⁰, or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode STATIC 20061017. (CONF-359)
 - [OCL]: `self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.6.88' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.6.59' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.6.96'`
6. 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-360)
 - UNIMPLEMENTABLE
7. 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-361)
 - UNIMPLEMENTABLE
8. 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-362)
 - UNIMPLEMENTABLE
9. **SHALL** satisfy: A manufacturedMaterial in a product template contains exactly one code / originalText, which represents the generic name of the product. (CONF-363)
 - [OCL]: `not self.manufacturedMaterial.code.originalText.ocIsUndefined()`
10. **MAY** satisfy: A manufacturedMaterial in a product template contains exactly one name, which represents the brand name of the product. (CONF-364)
 - [OCL]: `not self.manufacturedMaterial.name.ocIsUndefined()`
11. **MAY** satisfy: contains exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF-365)
 - [OCL]: `self.manufacturerOrganization->size() = 1`
12. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct **SHOULD** also contain manufacturedProduct / manufacturerOrganization. (CONF-367)
 - [OCL]: `self.id->size() > 0 implies self.manufacturerOrganization->size() > 0`
13. **SHALL** contain [1..1] code/@code, which **SHALL** be selected from ValueSet x.x.x Vaccine Administered (Pertussis)

Pertussis Immunization Product example

Chapter

6

VALUE SETS

Topics:

- [*Antibiotic Received \(Pertussis\)*](#)
- [*Lab Test Name \(Pertussis\)*](#)
- [*Signs and Symptoms \(Pertussis\)*](#)
- [*Transmission Setting*](#)
- [*Vaccine Administered \(Pertussis\)*](#)

The following tables summarize the value sets used in this Implementation Guide.

Antibiotic Received (Pertussis)

Value Set	Antibiotic Received (Pertussis) - 2.16.840.1.114222.4.11.3120
Code System	RxNorm - 2.16.840.1.113883.6.88
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3120
Definition	Antibiotic patient received for Pertussis answer list

Concept Code	Concept Name	Code System	Description
723	Amoxicillin	RxNorm	
19711	Amoxicillin / Clavulanate	RxNorm	
733	Ampicillin	RxNorm	
18631	Azithromycin	RxNorm	
2194	Cefuroxime	RxNorm	
2551	Ciprofloxacin	RxNorm	
21212	Clarithromycin	RxNorm	
3640	Doxycycline	RxNorm	
4053	Erythromycin	RxNorm	
70618	Penicillin	RxNorm	
10395	Tetracycline	RxNorm	
10831	Sulfamethoxazole / Trimethoprim	RxNorm	

Lab Test Name (Pertussis)

Value Set	Lab Test Name (Pertussis) - 2.16.840.1.114222.4.11.4184
Code System	LOINC - 2.16.840.1.113883.6.1
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.4184
Definition	lab tests associated with Pertussis

Signs and Symptoms (Pertussis)

Value Set	Signs and Symptoms (Pertussis) - 2.16.840.1.114222.4.11.6016
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6016

Concept Code	Concept Name	Code System	Description
49727002	Cough	SNOMEDCT	
284523002	Persistent cough	SNOMEDCT	
60537006	Whooping respiration	SNOMEDCT	
43025008	Paroxysms of coughing	SNOMEDCT	
422400008	Vomiting	SNOMEDCT	
424580008	Post-tussive vomiting	SNOMEDCT	
1023001	Apnea	SNOMEDCT	
3415004	Cyanosis	SNOMEDCT	
233604007	Pneumonia	SNOMEDCT	
70995007	Pulmonary Hypertension	SNOMEDCT	
91175000	Seizures	SNOMEDCT	
44186003	Dyssomnia	SNOMEDCT	
405737000	Pharyngitis	SNOMEDCT	
304213008	Low grade pyrexia	SNOMEDCT	
76067001	Sneezing	SNOMEDCT	
60119000	Exhaustion	SNOMEDCT	
267102003	Sore throat	SNOMEDCT	
81308009	Acute Encephalopathy	SNOMEDCT	

Transmission Setting

Value Set	Transmission Setting - 2.16.840.1.114222.4.11.1052
Source	PHIN VADS
Source URL	https://phinivads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1052
Definition	Location where the patient was exposed to the illness

Concept Code	Concept Name	Code System	Description
C1510656	Athletics	UMLS	
224864007	College	SNOMEDCT	
133928008	Community	SNOMEDCT	
1348009	Day care center	SNOMEDCT	
ER	Hospital ER	RoleCode	
264362003	Home	SNOMEDCT	
C0029916	Hospital Outpatient Clinic	UMLS	
PHC179	International Travel	PHIN VS	

Concept Code	Concept Name	Code System	Description
PHC64	Military	(CDC Local Coding System) PHIN VS (CDC Local Coding System)	
257656006	Penal institution	SNOMEDCT	
257659004	Place of worship	SNOMEDCT	
257698009	School	SNOMEDCT	
83891005	Solo practice private office	SNOMEDCT	
225746001	Ward	SNOMEDCT	
285141008	Work environment	SNOMEDCT	

Vaccine Administered (Pertussis)

Value Set	Vaccine Administered (Pertussis) - 2.16.840.1.114222.4.11.6015
Code System	Vaccines administered (CVX) - 2.16.840.1.113883.6.59
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6015

Concept Code	Concept Name	Code System	Description
01	DTP	Vaccines administered (CVX)	
11	Pertussis	Vaccines administered (CVX)	
20	DTaP	Vaccines administered (CVX)	
22	DTP-Hib	Vaccines administered (CVX)	
50	DTaP-Hib	Vaccines administered (CVX)	

Concept Code	Concept Name	Code System	Description
102	DTP-Hib-Hep B	Vaccines administered (CVX)	
106	DTaP, 5 pertussis antigens	Vaccines administered (CVX)	
107	DTaP, unspecified formulation	Vaccines administered (CVX)	
110	DTaP-IPV-HepB	Vaccines administered (CVX)	
115	Tdap	Vaccines administered (CVX)	
120	DTaP-IPV-Hib	Vaccines administered (CVX)	
130	DTaP-IPV	Vaccines administered (CVX)	
146	DTaP,IPV,Hib,HepB	Vaccines administered (CVX)	

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