

Implementation Guide for CDA Release 2 Toxic Shock Syndrome 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:

- [*Toxic Shock Syndrome Case Report*](#)

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

Toxic Shock Syndrome Case Report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.6]

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 exactly one [1..1] **title** = "Public Health Case Report - Toxic Shock Syndrome"
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:914, CONF:915), such that
 - a. Contains exactly one [1..1] *Phcr Social History Section* (templateId: 2.16.840.1.113883.10.20.15.2.22)
13. **SHOULD** contain zero or one [0..1] **component** (CONF:742, CONF:674), such that
 - a. Contains exactly one [1..1] *Phcr Treatment Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.4)
14. **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)
15. **MAY** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *CCD Immunizations Section* (templateId: 2.16.840.1.113883.10.20.1.6)
16. **SHALL** contain exactly one [1..1] **component**, such that
 - a. Contains exactly one [1..1] *Tss Phcr Clinical Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.42)
17. **SHOULD** contain zero or one [0..1] **component**, such that
 - a. Contains exactly one [1..1] *Tss Phcr Relevant Dx Tests Section* (templateId: 2.16.840.1.113883.10.20.15.2.43)
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)

Toxic Shock Syndrome Case Report example

Chapter

3

SECTION TEMPLATES

Topics:

- *Tss Phcr Clinical Information Section*
 - *Tss Phcr Relevant Dx Tests Section*
-

Tss Phcr Clinical Information Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.42]

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] [Tss Case Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.99)
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))
```

Tss Phcr Clinical Information Section example

## Tss Phcr Relevant Dx Tests Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.43]

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. **MAY** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Tss Result Organizer* (templateId: 2.16.840.1.113883.10.20.15.3.101)
8. **SHOULD** contain zero or more [0..\*] **entry**, such that
  - a. Contains **@typeCode**="DRIV" *DRIV (is derived from)*
  - b. Contains exactly one [1..1] *Tss Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.102)
9. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
  - UNIMPLEMENTABLE

#### Tss Phcr Relevant Dx Tests Section example



---

# Chapter

# 4

---

## CLINICAL STATEMENT TEMPLATES

---

### Topics:

- [\*Tss Case Observation\*](#)
- [\*Tss Result Observation\*](#)
- [\*Tss Result Organizer\*](#)
- [\*Tss Signs And Symptoms Observation\*](#)

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.

## Tss Case Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.99]

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**="240450004" (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT), where its data type is CD (CONF:1874)
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 **@typeCode**="MFST" *MFST (is manifestation of)*
  - b. Contains exactly one [1..1] [Tss Signs And Symptoms Observation](#) (templateId: 2.16.840.1.113883.10.20.15.3.100)
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.ocIsKindOf(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)

### Tss Case Observation example

## Tss Result Observation

---

[Observation: templateId 2.16.840.1.113883.10.20.15.3.102]

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 *Lab Test Result Name (Tss)* **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'))`

### Tss Result Observation example

## Tss Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.101]

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**, which **SHALL** be selected from ValueSet *Lab Test Result Name (Tss)* **DYNAMIC**
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] *Tss Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.102)
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)
```

Tss Result Organizer example

Tss Signs And Symptoms Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.100]

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 *Signs and Symptoms (Tss)* **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)

Tss Signs And Symptoms Observation example

Chapter

5

OTHER CLASSES

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

Chapter

6

VALUE SETS

Topics:

- [Lab Test Result Name \(Tss\)](#)
- [Signs and Symptoms \(Tss\)](#)

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

Lab Test Result Name (Tss)

Value Set	Lab Test Result Name (Tss) - (OID not specified)		
Code System	LOINC - 2.16.840.1.113883.6.1		
Source	PHIN VADS		

Concept Code	Concept Name	Code System	Description
11468-6	Bacillus anthracis Ab:ACnc:Pt:XXX:Qn:IF	LOINC	
33697-4	Bacillus anthracis Ag:ACnc:Pt:Isolate:Ord:IF	LOINC	
22866-8	Bacillus anthracis Ag:ACnc:Pt:Tiss:Ord:IF	LOINC	
22867-6	Bacillus anthracis Ag:ACnc:Pt:XXX:Ord:IF	LOINC	
51976-9	Bacillus anthracis capsule Ag:Prid:Pt:XXX:Nom:IF	LOINC	
44269-9	Bacillus anthracis cell wall Ag:Prid:Pt:XXX:Nom:IF	LOINC	
33698-2	Bacillus anthracis:ACnc:Pt:Isolate:Ord:Phage lysis	LOINC	
44270-7	Bacillus anthracis spore Ag:Prid:Pt:XXX:Nom:IF	LOINC	
11469-4	Bacillus anthracis:ACnc:Pt:XXX:Ord:Organism specific culture	LOINC	
17928-3	Bacteria identified:Prid:Pt:Bld:Nom:Aerobic culture	LOINC	
17915-0	Bacteria identified:Prid:Pt:Wound.shlw:Nom:Aerobic culture	LOINC	
622-1	Bacteria identified:Prid:Pt:Sputum:Nom:Aerobic culture	LOINC	
21020-3	Bacteria identified:Prid:Pt:XXX:Nom:Anaerobic +Aerobic culture	LOINC	
41622-2	B anthracis DNA XXX PCR	LOINC	

Signs and Symptoms (Tss)

Value Set	Signs and Symptoms (Tss) - (OID not specified)		
Source	PHIN VADS		

Concept Code	Concept Name	Code System	Description
21522001	Abdominal pain	SNOMEDCT	
84387000	Asymptomatic	SNOMEDCT	
29857009	Chest pain	SNOMEDCT	
43724002	Chill	SNOMEDCT	
PHC819	Cutaneous ulcer with edema and black eschar	PHIN VS (CDC Local Coding System)	
62315008	Diarrhea	SNOMEDCT	
230145002	Difficulty breathing	SNOMEDCT	
267038008	Edema	SNOMEDCT	
386661006	Fever	SNOMEDCT	
25064002	Headache	SNOMEDCT	
30746006	Lymphadenopathy	SNOMEDCT	
409596002	Non-productive cough	SNOMEDCT	

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- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: [Quality Reporting Document Architecture \(QRDA\)](#)
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through [HL7](#) .
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- [LOINC®](#) : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
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- 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](#)

