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**HL7 Cross Paradigm Implementation Guide:**  
**Sex and Gender Representation Release 1**  
**CDA STU 1 Ballot Section**

September 2022

**HL7 Normative Ballot**

**Sponsored by:**  
**Vocabulary Work Group**  
**Patient Administration Work Group**  
**Patient Care Work Group**  
**Public Health Work Group**

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# Table of Contents

1 INTRODUCTION .....5

2 ENTRY .....7

2.1 Gender Identity GH .....7

2.2 Individual Pronouns.....8

2.3 Recorded Sex or Gender ..... 10

2.4 Sex for Clinical Use ..... 15

3 VALUE SETS IN THIS GUIDE ..... 18

4 CODE SYSTEMS IN THIS GUIDE..... 19

5 EXAMPLE .....20

# Table of Figures

Figure 1: Gender Identity Observation Example ..... 8

Figure 2: Gender Identity Observation Example ..... 10

Figure 3: Recorded Sex or Gender..... 14

Figure 4: Sex for Clinical Use ..... 17

# Table of Tables

Table 1: Gender Identity Core Concepts ..... 8

Table 2: Asked but Unknown and Other ..... 8

Table 3: Pronouns ..... 9

Table 4: international-civil-aviation-organization-sex-or-gender ..... 13

Table 5: sex-for-clinical-use ..... 17

Table 6: Value Sets ..... 18

Table 7: Code Systems..... 19

# 1 INTRODUCTION

## Overview

This guide provides entry templates to support the representation of sex and gender as proposed in the Gender Harmony logical model in forms that can be unambiguously translated among HL7 V2, CDA, and FHIR representations.

It does not provide a document template, and it does not specify what documents or document sections should contain these templates. The templates can be adopted by any organization that finds them useful, in any way it finds useful. It is expected that the Gender Identity, Pronouns, and Recorded Sex or Gender entries will be contained in a Social History section, but this is not a constraint. The Sex for Clinical Use template has its own rules for where it should be used.

As most guides specify “open” templates, inclusion of these entries where appropriate should be feasible. In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

Open templates allow HL7 implementers to develop additional structured content not defined within any specific guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

The Gender Identity template is very similar to an existing template in the C-CDA companion guide, which many may have already implemented. The new template was designed to be compatible with the prior one, so it is feasible to use both template IDs in a template instance, as long as it conforms to both.

Sex for Clinical Use (SFCU) contextualizes clinical operations. It may constrain the execution of a specific intervention or affect the interpretation of a specific result. The target activity scopes the validity of the observation. The complex requirement is to associate the SFCU observation with the appropriate targets.

CDA supports multiple approaches for asserting relationships among entries.

Putting the SFCU observation in a section with the entries it constrains would not imply the required information. Document sections do not carry or imply semantics.

One approach would be to use the Entry Reference template to associate an SFCU with those entries to which it applies. This is a quite flexible approach, but it may rely on a level of sophistication that not all implementers can support, and it makes visual rendering difficult.

The template describes the appropriate approach (using entryRelationship) for establishing context specific to one or more entries, to an encounter, or to the patient generally. This approach leverages context conduction appropriately, and it is a tactic with which many implementers are familiar.

## Modeling Approach

To support the content defined in the Gender Harmony logical model in CDA, two primary design approaches were considered: the “core model change” option, where the CDA model would be extended by defining new types and relations in the SDTC extension schema, and the “name-value” option, where templates could be defined to specify data elements as Observations with codes and values.

Both the FHIR and V2 efforts chose to build this information into the core model – as FHIR extensions in FHIR and as a new segment in V2 – because the information processing requirements that those standards support benefit from this proximity. In FHIR, for instance, an extension on Patient is

included in the Patient resource instance and is available to any client with access to the Patient, whereas using an Observation would require clients to traverse the Observation reference, and possibly to modify the scope of authorization needed to do so.

CDA does not have this constraint. While the xpath of an Observation entry is longer than the xpath of a Patient property, all of the content of a document is integrally and holistically included in the document. The primary criterion, then, was ease of use and access to the artifacts. Since implementers are familiar with the process of processing clinical statements, their technologies handle additions to these clinical statement templates frequently, and the means of publishing these templates presents the complete design to stakeholders (without requiring inspection of xsd hierarchy), the clinical statement template was judged the most feasible approach.

One concern was translation: would adopting the “name-value” option in CDA create difficulties translating from and to specifications that adopted the “core model change” option? The answer is that the use of the name-value pattern does not add significantly to the complexity of mapping across the specification formats.

### **Semantic Scope**

Four of the five elements are patient-specific: limits on their scope can be managed with the effectiveTime property. Sex for Clinical Use, however, can be scoped to specific procedures, observations, encounters, and other objects. Methods for associating this observation with its targets are outlined in the template description.

#### Notes for balloters

1. Is more directive guidance warranted for what kinds of artifacts may include these entry templates?
2. Is “derivationExpr” an appropriate representation of a natural language definition, or should that property of Recorded Sex or Gender be another sub-entry?
3. Every effort has been made to ensure that Sex for Clinical Use is flexible enough to support a variety of use cases. However, the cases tend to fall into two classes: reference ranges for interpreting findings and context constraining the execution of a procedure. The latter is rare in clinical documents. Is this level of flexibility necessary or appropriate for this context?

## 2 ENTRY

### 2.1 Gender Identity GH

[observation: identifier urn:oid:2.16.840.1.113883.10.15.1 (open)]

An individual's personal sense of being a man, woman, boy, girl, nonbinary, or something else. This represents an individual's identity, ascertained by asking them what that identity is.

This observation is not appropriate for recording administrative gender or birth sex.

This template represents one code value, with associated context and metadata. It is expected to be composed into containing structures with multiple cardinality to support cases that require multiple values.

This template is designed to be aligned with <http://build.fhir.org/extension-individual-genderidentity.html>.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192739)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192740)
3. **SHALL** contain exactly one [1..1] **templateId** **STATIC** (CONF:192729) such that it
  - a. **SHALL** contain exactly one [1..1] **@root** **STATIC**="2.16.840.1.113883.10.15.1" (CONF:192734)
  - b. **SHALL** contain zero or one [0..1] **@extension**="2022-09-01" (CONF:192735)
4. **SHALL** contain exactly one [1..1] **code** (CONF:192730)
  - a. **SHALL** contain exactly one [1..1] **@code** **STATIC**="76691-5" Gender identity (CONF:192736)
  - b. **SHALL** contain exactly one [1..1] **@codeSystem**, which **SHALL** be selected from CodeSystem LOINC (urn:oid:2.16.840.1.113883.6.1) **STATIC**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192737)
5. **MAY** contain zero or one [0..1] **text** (CONF:192935)
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:192732)
  - a. **SHALL** contain exactly one [1..1] **@code**="completed" (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192741)
7. **MAY** contain exactly one [1..1] **effectiveTime** (CONF:192733)
8. **SHALL** contain exactly one [1..1] **value/@code**, which **SHALL** be selected from ValueSet Gender Identity Core Concepts urn:oid:2.16.840.1.113762.1.4.1021.106 **DYNAMIC** (CONF:192731)

To represent additional Gender Identities, instantiate another entry, set nullFlavor="OTH", and use originalText or translation. To represent "choose not to disclose", set nullFlavor="ASKU".

- a. **MAY** contain zero or one [0..1] **@nullFlavor**, which **MAY** be selected from ValueSet Asked but Unknown and Other urn:oid:2.16.840.1.113762.1.4.1114.17 **DYNAMIC** (CONF:192738)

**Table 1: Gender Identity Core Concepts**

Value Set: Gender Identity Core Concepts urn:oid:2.16.840.1.113762.1.4.1021.106			
Code	Code System	Code System OID	Print Name
446141000124107	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as female gender (finding)
446151000124109	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as male gender (finding)
33791000087105	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as nonbinary gender (finding)

**Table 2: Asked but Unknown and Other**

Value Set: Asked but Unknown and Other urn:oid:2.16.840.1.113762.1.4.1114.17 (Clinical Focus: Data absent reasons specific for representing only asked but unknown and other),(Data Element Scope: any data representation that supports inclusion of data absent reasons),(Inclusion Criteria: Asked but no answer known and Other meant to mean data not available for selection),(Exclusion Criteria: all other codes)  This value set was imported on 6/17/2022 with a version of Latest. Value Set Source: <a href="https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion">https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion</a>			
Code	Code System	Code System OID	Print Name
ASKU	HL7NullFlavor	urn:oid:2.16.840.1.113883.5.1008	asked but unknown
OTH	HL7NullFlavor	urn:oid:2.16.840.1.113883.5.1008	other

**Figure 1: Gender Identity Observation Example**

<pre> &lt;observation classCode="OBS" moodCode="EVN"&gt;   &lt;templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01"/&gt;   &lt;code code="76691-5" codeSystem="2.16.840.1.113883.6.1"     displayName="Gender Identity"/&gt;   &lt;statusCode code="completed"/&gt;   &lt;value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"     codeSystemName="SNOMED CT" code="446151000124109"     displayName="Identifies as male gender"&gt;   &lt;/value&gt; &lt;/observation&gt; </pre>
--

## 2.2 Individual Pronouns

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.2:2022-09-01  
(open) ]

Pronoun(s) specified by the patient to use when referring to the patient in speech, in clinical notes, and in written instructions to caregivers.



Designed to conform to <https://build.fhir.org/ig/HL7/fhir-gender-harmony/branches/main/StructureDefinition-pronouns.html>

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192860)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192861)
3. **SHALL** contain exactly one [1..1] **templateId STATIC** (CONF:192849) such that it
  - a. **SHALL** contain exactly one [1..1] **@root STATIC="2.16.840.1.113883.10.15.2"** (CONF:192853)
  - b. **SHALL** contain zero or one [0..1] **@extension="2022-09-01"** (CONF:192854)
4. **SHALL** contain exactly one [1..1] **code** (CONF:192850)
  - a. **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from CodeSystem LOINC (urn:oid:2.16.840.1.113883.6.1) **STATIC="90778-2" Personal pronouns – Reported** (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192855)
5. **MAY** contain zero or one [0..1] **text** (CONF:192862)
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:192852)
  - a. **SHALL** contain exactly one [1..1] **@code="completed"** (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192858)
7. **MAY** contain exactly one [1..1] **effectiveTime** (CONF:192859)
8. **SHOULD** contain exactly one [1..1] **value/@code**, which **SHOULD** be selected from ValueSet Pronouns urn:oid:2.16.840.1.113883.11.19755 **DYNAMIC** (CONF:192851)

To represent additional Gender Identities, set nullFlavor="OTH". To represent "choose not to disclose", set nullFlavor="ASKU".

- a. **MAY** contain zero or one [0..1] **@nullFlavor**, which **MAY** be selected from ValueSet Asked but Unknown and Other urn:oid:2.16.840.1.113762.1.4.1114.17 **DYNAMIC** (CONF:192857)

**Table 3: Pronouns**

Value Set: Pronouns urn:oid:2.16.840.1.113883.11.19755 This value set defines a set of codes that can be used to indicate the pronouns used to communicate about an individual. Value Set Source: <a href="http://build.fhir.org/valueset-pronouns.html">http://build.fhir.org/valueset-pronouns.html</a>			
Code	Code System	Code System OID	Print Name
LA29518-0	LOINC	urn:oid:2.16.840.1.113883.6.1	He, Him, His, Himself
LA29519-8	LOINC	urn:oid:2.16.840.1.113883.6.1	She, Her, Hers, Herself
LA29520-6	LOINC	urn:oid:2.16.840.1.113883.6.1	They, Them, Their, Theirs, Themselves

**Figure 2: Gender Identity Observation Example**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.15.2" extension="2022-09-01"/>
  <code code="90778-2" codeSystem="2.16.840.1.113883.6.1"
    displayName="Personal pronouns"/>
  <statusCode code="completed"/>
  <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" code="LA29518-0"
    displayName="He, Him, His, Himself"/>
</observation>
```

## 2.3 Recorded Sex or Gender

[observation: identifier urn:oid:2.16.840.1.113883.10.15.4 (open)]

The recorded sex and gender is to be used to represent sex or gender data from a document or record where the meaning is unclear, the meaning is different from the semantics specified in the Gender Identity and Sex for Clinical Use templates, or for which the source is significant. For example, the individual's birth certificate information, passport information, and national identity document information may all be present. This is necessary because an individual's documents may be updated at different rates or for different reasons. Sex assigned at birth (SAAB), while very common and considered essential in some jurisdictions, is considered a recorded sex and gender entry.

The entry relationships are to Observations representing

- The jurisdiction or organization that issued the document from which the sex or gender was acquired
- The date/time when the sex or gender value was first recorded in the system.
- The type of source document where this sex or gender property is initially recorded.
- The description of the data element within the source document

This template is designed to support correspondence with <http://build.fhir.org/extension-individual-recordedsexorgender.html>.

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192876)
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192877)
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:192878) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.15.4"** (CONF:192879)
  - b. **SHALL** contain zero or one [0..1] **@extension="2022-09-01"** (CONF:192880)
4. **SHALL** contain exactly one [1..1] **code** (CONF:192881)
  - a. **SHALL** contain exactly one [1..1] **@code="99502-7"** Recorded sex or gender (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192889)

originalText is the name of the field in the source document.

- b. **MAY** contain zero or one [0..1] **originalText** (CONF:192882)

derivationExpr is used to record the algorithm or rationale for the assignment.

5. **MAY** contain zero or one [0..1] **derivationExpr** (CONF:192937)
6. **MAY** contain zero or one [0..1] **text** (CONF:192883)
7. **SHALL** contain exactly one [1..1] **statusCode="completed"** Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192884)
8. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:192886)

The value element should contain the recorded sex or gender value. If it is encoded, the code and system should be captured; if it is from a document, it's likely it will consist of originalText only.

9. **SHALL** contain exactly one [1..1] **value** (CONF:192885)
  - a. **MAY** contain zero or one [0..1] **translation**, which **MAY** be selected from ValueSet international-civil-aviation-organization-sex-or-gender urn:oid:2.16.840.1.113883.11.19756 (CONF:192887)

Jurisdiction is the organization that issued the document and therefore defines the concept. Typically a state or nation, but possibly a firm or professional society.

10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:192899) such that it
  - a. **SHALL** contain exactly one [1..1] **observation** (CONF:192900)
    - i. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192902)
    - ii. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192903)
    - iii. **SHALL** contain exactly one [1..1] **code="77969-4"** Jurisdiction code (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192901)
    - iv. **SHALL** contain exactly one [1..1] **statusCode="complete"** Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192904)
    - v. **SHALL** contain exactly one [1..1] **value** (CONF:192905)
      1. **MAY** contain zero or one [0..1] **originalText** (CONF:192906)

Document Type is the type of artifact capturing the recorded sex or gender; e.g., birth certificate, passport, or EHR.

11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:192907) such that it
  - a. **SHALL** contain exactly one [1..1] **observation** (CONF:192908)
    - i. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192909)
    - ii. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192910)
    - iii. **SHALL** contain exactly one [1..1] **code="92183-3"** Document type (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192911)
    - iv. **SHOULD** contain exactly one [1..1] **statusCode="completed"** Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192912)
    - v. **SHALL** contain exactly one [1..1] **value** (CONF:192913)

1. **MAY** contain zero or one [0..1] **originalText** (CONF:192914)

Date of Entry is the date that the document was scanned, processed, etc. to extract the sex or gender information, not the date the document was created.

12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:192915) such that it
  - a. **SHALL** contain exactly one [1..1] **observation** (CONF:192916)
    - i. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192918)
    - ii. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192919)
    - iii. **SHALL** contain exactly one [1..1] **code="50786-3"** Date of entry (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192917)
    - iv. **SHALL** contain exactly one [1..1] **value with @xsi:type="TS"** (CONF:192920)

Element Type characterizes the field containing the recorded sex or gender. If the value comes from an EHR, it may be encoded (e.g., "76689-9 sex assigned at birth"). If it comes from a paper form, use the root Observation.code.originalText. If the value has both code and label, use both the root originalText and originalText on this coded Observation to record the field label.

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:192922) such that it
  - a. **SHALL** contain exactly one [1..1] **observation** (CONF:192923)
    - i. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192924)
    - ii. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192925)
    - iii. **SHALL** contain exactly one [1..1] **code="TempElementType"** Element (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192926)
    - iv. **MAY** contain zero or one [0..1] **text** (CONF:193003)
    - v. **SHALL** contain exactly one [1..1] **statusCode="complete"** Complete (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192927)
    - vi. **SHALL** contain exactly one [1..1] **value** (CONF:192928)
      1. **SHALL** contain zero or one [0..1] **@code** (CONF:193037)
      2. **MAY** contain zero or one [0..1] **originalText** (CONF:193038)

If the source document can be represented and linked electronically, it can be supported via ExternalDocument/text@data or ExternalDocument/text@reference.

14. **MAY** contain zero or one [0..1] **reference** (CONF:192921)

**Table 4: international-civil-aviation-organization-sex-or-gender**

Value Set: international-civil-aviation-organization-sex-or-gender urn:oid:2.16.840.1.113883.11.19756 The complete set of concepts used for exchange of the 'sex' value as represented in international travel documents as defined by Doc 9303: Machine Readable Travel Documents, Part 7: Machine Readable Visas published by the International Civil Aviation Organization (ICAO). Initially aligned with the Eighth Edition (2021). Value Set Source: <a href="http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html">http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html</a>			
Code	Code System	Code System OID	Print Name
F	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.64 2.1.0	Female
M	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.64 2.1.0	Male
<	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.64 2.1.0	X

**Figure 3: Recorded Sex or Gender**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.15.4" extension="2022-09-01"/>
  <code code="99502-7" codeSystem="2.16.840.1.113883.6.1"
    displayName="Recorded sex or gender"/>
  <derivationExpr>Enter whether the infant is male, female, or if the sex
    of the infant is ambiguous, enter "unknown."</derivationExpr>
  <statusCode code="completed"/>
  <value xsi:type="CD" code="F">
    <translation code="F" codeSystem="2.16.840.1.113883.11.19756"
      codeSystemName="International Civil Aviation Organization Sex or Gender"
      displayName="Female"/>
  </value>
</observation>
<entryRelationship typeCode="COMP">
  <!-- Jurisdiction -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="77969-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Jurisdiction code"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" nullFlavor="OTH" codeSystem="NP">
      <!-- This may be coded but does not have to be -->
      <originalText>California</originalText>
    </value>
  </observation>
</entryRelationship>
<entryRelationship typeCode="COMP">
  <!-- Document Type -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="92183-3" codeSystem="2.16.840.1.113883.6.1"
      displayName="Document type"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="71230-7"
      displayName="Birth Certificate"/>
  </observation>
</entryRelationship>
<entryRelationship typeCode="COMP">
  <!-- Date of Entry -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="50786-3" codeSystem="2.16.840.1.113883.6.1"
      displayName="Date of entry"/>
    <statusCode code="completed"/>
    <value xsi:type="TS" value="201201011450+0600"/>
  </observation>
</entryRelationship>
<!-- Element Type -->
<entryRelationship>
  <observation classCode="OBS" moodCode="EVN">
    <code code="TempElementType" codeSystem="2.16.840.1.113883.6.1"
      displayName="Element type"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="76689-9"
      displayName="Sex assigned at birth"/>
  </observation>
</entryRelationship>
```

## 2.4 Sex for Clinical Use

[observation: identifier urn:oid:2.16.840.1.113883.10.15.3 (open)]

Sex for Clinical Use (SFCU) is a categorization of sex derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc., or from interventions with relevant effects such as hormone therapy. This property is intended for use in clinical decision making and indicates that treatment or diagnostic tests should consider best practices associated with the relevant reference population.

While clinical decision-making processes could support inference of specific physiological or anatomical attributes of the patient, there are several practical considerations, such as patient privacy and limited capabilities of existing systems which create the need for a categorization that is easy to exchange. The SFCU categorization is intended to bridge the gap between the hypothetical ideal and the practical needs of operational systems. "Prescription for testosterone" is not an SFCU value, though it may be a supporting observation for one.

This template is designed to support correspondence with <http://build.fhir.org/extension-patient-sexforclinicaluse.html>

SFCU is a contextual concept. For example, a patient may generally be categorized as male, but for a specific lab test, the resulting lab should use the reference ranges associated with a female reference population. In this case, systems may annotate the lab order with a context-specific SFCU. Systems may determine what enclosing contexts are useful, but Patient, entry, and encounter are three contexts that may often apply.

Clinical scenarios include setting up procedures and interpreting results. For the procedure case, SFCU will be needed on the order, and it may be carried on subsequent descriptions of the procedure. Note that the order concept in CDA is referenced by the somewhat concise Order class, which, being in the header, does not support SFCU. More detailed descriptions of the Procedure or SubstanceAdministration in the body will support SFCU. Since documents are not typically used to place orders, this does not seem to present a problem.

For the results scenario, relevant SFCU observations should be carried on result Observations just as a reference range would be.

### Evidence

SFCU observations may be based on clinical evidence documented elsewhere in the document. These relationships are supported by Entry Relationships.

### Establishing context

Context is established for an **entry**-specific SFCU observation by nesting it under its target entry using entryRelationship. This approach uses CDA Context Conduction to manage scope appropriately: the observation is a component of the enclosing entry with no implication of relevance outside of that entry.

This means that, in cases where one SFCU observation pertains to multiple entries, an implementer should use an Entry Reference to assert other instances of the relationship. In these cases, the Entry Reference should be a sub-entry of the target, not the SFCU, with entryRelationship.typeCode "COMP" to indicate subordination to the entry of interest.

In cases where the SFCU Observation pertains to an entire **encounter**, an encounter entry can be used to contain the SFCU observation. Note that the entry is required: the header `EncompassingEncounter` cannot contain entries.

In cases where the SFCU Observation pertains to the **patient** categorically, in all contexts, it can be included as an independent entry (placed in, e.g., a Social History section), where its independence from a containing entry implies general applicability to the patient. In this scenario, entries do not need to identify the observation explicitly.

In no case should SFCU pertain to a **document**, unless incidentally by one of the tactics described above. A document has a clinical context, but it does not establish a clinical context. In a procedure note, for instance, the SFCU may pertain to the procedure itself, not the document.

### Values

The “male” and “female” values indicate that the patient is meets the criteria for that value in the context of the identified entry; e.g., “use the male reference range.”

The “unknown” value means that a determination cannot be made.

The “specified” value indicates that such an assignment cannot be made but that relevant data is specified elsewhere, e.g., in a medication order for hormone therapy that is not sufficient to change the value to from one binary value to the other, but that does indicate caution in using either assumption. In such a case the relevant specification **SHOULD** be associated with the SFCU as “support” (“SPRT”).

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:192866)
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:192867)
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:192868) such that it
  - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.15.3"` (CONF:192869)
  - b. **SHALL** contain zero or one [0..1] `@extension="2022-09-01"` (CONF:192870)
4. **SHALL** contain exactly one [1..1] `code="99501-9"` Sex for clinical use (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:192871)
5. **MAY** contain zero or one [0..1] `text` (CONF:192872)
6. **SHALL** contain exactly one [1..1] `statusCode="complete"` Complete (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:192873)
7. **SHOULD** contain zero or one [0..1] `effectiveTime` (CONF:192874)
8. **SHALL** contain exactly one [1..1] `value/@code`, which **SHALL** be selected from ValueSet `sex-for-clinical-use` urn:oid:2.16.840.1.113883.4.642.3.982 (CONF:192875)
9. **MAY** contain zero or more [0..\*] `entryRelationship` (CONF:192893) such that it

This Entry Reference associates the assertion of Sex for Clinical Use with supporting clinical data - Observations, Procedures, SubstanceAdministrations, or other entries that support or explain the assignment.

- a. **SHALL** contain exactly one [1..1] `@typeCode="SPRT"` has support (CONF:192896)
- b. **SHALL** contain exactly one [1..1] `act` (CONF:192894)



**Table 5: sex-for-clinical-use**

Value Set: sex-for-clinical-use urn:oid:2.16.840.1.113883.4.642.3.982 This value set defines a set of codes that can be used to indicate a patient's sex for clinical use. Value Set Source: <a href="http://build.fhir.org/valueset-sex-for-clinical-use.html">http://build.fhir.org/valueset-sex-for-clinical-use.html</a>			
Code	Code System	Code System OID	Print Name
female	Sex For Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.982	Female sex for clinical use
male	Sex For Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.982	Male sex for clinical use
specified	Sex For Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.982	Specified sex for clinical use
unknown	Sex For Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.982	Unknown

**Figure 4: Sex for Clinical Use**

<pre> &lt;observation classCode="OBS" moodCode="EVN"&gt;   &lt;templateId root="2.16.840.1.113883.10.15.3"     extension="2022-09-01"/&gt;   &lt;code code="99501-9" codeSystem="2.16.840.1.113883.6.1"     displayName="Sex for clinical use"/&gt;   &lt;statusCode code="completed"/&gt;   &lt;value xsi:type="CD"     codeSystem="2.16.840.1.113883.4.642.1.983"     codeSystemName="Sex For Clinical Use" code="female"     displayName="Female sex for clinical use"&gt;   &lt;/value&gt;   &lt;!-- Supporting Reference for Sex for Clinical Use --&gt;   &lt;entryRelationship typeCode="SPRT"&gt;     &lt;act classCode="ACT" moodCode="EVN"&gt;       &lt;templateId root="2.16.840.1.113883.10.20.22.4.122"/&gt;       &lt;id root="6C844C75-AA34-411C-B7BD-5E4A9F206E29"/&gt;       &lt;code nullFlavor="OTH" codeSystem="NP"/&gt;       &lt;statusCode code="completed"/&gt;     &lt;/act&gt;   &lt;/entryRelationship&gt; &lt;/observation&gt; </pre>
--

### 3 VALUE SETS IN THIS GUIDE

**Table 6: Value Sets**

<b>Name</b>	<b>OID</b>	<b>URL</b>
<a href="#">Asked but Unknown and Other</a>	urn:oid:2.16.840.1.113762.1.4.1114.17	<a href="https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion">https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion</a>
<a href="#">Gender Identity Core Concepts</a>	urn:oid:2.16.840.1.113762.1.4.1021.106	N/A
<a href="#">international-civil-aviation-organization-sex-or-gender</a>	urn:oid:2.16.840.1.113883.11.19756	<a href="http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html">http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html</a>
<a href="#">Pronouns</a>	urn:oid:2.16.840.1.113883.11.19755	<a href="http://build.fhir.org/valueset-pronouns.html">http://build.fhir.org/valueset-pronouns.html</a>
<a href="#">sex-for-clinical-use</a>	urn:oid:2.16.840.1.113883.4.642.3.982	<a href="http://build.fhir.org/valueset-sex-for-clinical-use.html">http://build.fhir.org/valueset-sex-for-clinical-use.html</a>

## 4 CODE SYSTEMS IN THIS GUIDE

**Table 7: Code Systems**

<b>Name</b>	<b>OID</b>
HL7ActClass	urn:oid:2.16.840.1.113883.5.6
HL7ActMood	urn:oid:2.16.840.1.113883.5.1001
HL7ActStatus	urn:oid:2.16.840.1.113883.5.14
HL7NullFlavor	urn:oid:2.16.840.1.113883.5.1008
International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.642.1.0
LOINC	urn:oid:2.16.840.1.113883.6.1
Sex For Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.982
SNOMED CT	urn:oid:2.16.840.1.113883.6.96

## 5 EXAMPLE

This example was constructed to illustrate the use case provided in the September 2022 ballot. It provides all three “Social History” templates, and it also provides two different instances of the Sex for Clinical Use template, illustrating its flexibility. One SFCU instance also uses a SPRT Entry Reference, which is not specific to the use case, but is included to illustrate its purpose.

```
<?xml version="1.0"?>
<?xml-stylesheet type="text/xsl" href="CDA.xsl"?>
<!--
  Title: Sex for Clinical Use CDA Template Example file
  Version: 1.0
  Revision History:
  31-Jan-2011 source document created
  10-Aug-2022 example drafted [Jay Lyle, JP Systems for the VHA;
    Rob Horn, Fairhaven Technology;
    Steven Nichols, GE]
-->

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

*****
CDA Header
*****
-->

  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <!-- US General Header Template -->
  <templateId root="2.16.840.1.113883.10.20.22.1.1"/>
  <!-- Diagnostic Imaging Report Template -->
  <templateId root="2.16.840.1.113883.10.20.22.1.5"/>
  <id root="2.16.840.1.113883.19.4.27" extension="20060828170821659"/>
  <code code="18748-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="Diagnostic Imaging Report"/>
  <title>PET/CT Heart W contrast IV</title>
  <effectiveTime value="20050329171504+0500"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
  <languageCode code="en-US"/>
```

```

<setId extension="111199021" root="2.16.840.1.113883.19"/>
<versionNumber value="1"/>
<recordTarget>
  <!--NEW CONF per base CDA - patientRole SHALL be present of [1..*]-->
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19.5"/>
    <addr use="HP">
      <streetAddressLine>3300 Washtenaw Ave # 227</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(734)555-1212" use="HP"/>
    <patient>
      <name use="L">
        <given>Smith</given>
        <family>John</family>
      </name>
      <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19541125"/>
      <maritalStatusCode code="S" displayName="Single" codeSystem="2.16.840.1.113883.5.2"
        codeSystemName="MaritalStatusCode"/>
      <religiousAffiliationCode code="1013" displayName="Christian"
        codeSystemName="HL7 Religious Affiliation "
        codeSystem="2.16.840.1.113883.5.1076"/>
      <raceCode code="2106-3" displayName="White" codeSystem="2.16.840.1.113883.6.238"
        codeSystemName="Race & Ethnicity - CDC"/>
      <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
        codeSystem="2.16.840.1.113883.6.238" codeSystemName="Race & Ethnicity - CDC"/>
      <guardian>
        <code code="GRFTH" displayName="Grandfather"
          codeSystem="2.16.840.1.113883.5.111" codeSystemName="HL7 Role code"/>
        <addr use="HP">
          <streetAddressLine>3300 Washtenaw Ave # 227</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>48104</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:(734)555-1212" use="HP"/>
        <guardianPerson>
          <name>
            <given>Ralph</given>
            <family>Relative</family>
          </name>
        </guardianPerson>
      </guardian>
    </patient>
  </patientRole>

```

```

    </name>
  </guardianPerson>
</guardian>
<birthplace>
  <place>
    <addr>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
  </place>
</birthplace>
<languageCommunication>
  <languageCode code="fr-CN"/>
  <modeCode code="RWR" displayName="Recieve Written"
    codeSystem="2.16.840.1.113883.5.60" codeSystemName="LanguageAbilityMode"/>
  <preferenceInd value="true"/>
</languageCommunication>
</patient>
<providerOrganization>
  <id root="2.16.840.1.113883.19.5"/>
  <name>Good Imaging Clinic</name>
  <telecom value="tel:(734)555-1212"/>
  <addr>
    <streetAddressLine>21 North Ave</streetAddressLine>
    <city>Ann Arbor</city>
    <state>MI</state>
    <postalCode>48104</postalCode>
    <country>USA</country>
  </addr>
</providerOrganization>
</patientRole>
</recordTarget>
<author>
  <time value="20050329224411+0500"/>
  <assignedAuthor>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
  </assignedAuthor>
</author>

```

```

<assignedPerson>
  <name>
    <given>Bill</given>
    <family>Roentgen</family>
  </name>
</assignedPerson>
</assignedAuthor>
</author>
<dataEnterer>
  <assignedEntity>
    <id root="2.16.840.1.113883.19.5" extension="43252"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Bill</given>
        <family>Roentgen</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Imaging Clinic</name>
      <telecom value="tel:(555)555-1212" use="WP"/>
      <addr use="HP">
        <streetAddressLine>3300 Washtenaw Ave # 227</streetAddressLine>
        <city>Ann Arbor</city>
        <state>MI</state>
        <postalCode>48104</postalCode>
        <country>USA</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
<informationRecipient>
  <intendedRecipient>

```

```

<informationRecipient>
  <name>
    <given>Bill</given>
    <family>Roentgen</family>
  </name>
</informationRecipient>
<receivedOrganization>
  <name>Good Imaging Clinic</name>
</receivedOrganization>
</intendedRecipient>
</informationRecipient>
<legalAuthenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
  </assignedEntity>
  <assignedPerson>
    <name>
      <given>Bill</given>
      <family>Roentgen</family>
    </name>
  </assignedPerson>
</legalAuthenticator>
<authenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>48104</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
  </assignedEntity>
</authenticator>

```



```

    <assignedPerson>
      <name>
        <given>Bill</given>
        <family>Roentgen</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>
<inFulfillmentOf>
  <order>
    <id extension="10523475" root="1.2.840.113619.2.62.994044785528.27"/>
    <code code="121022" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
      displayName="Accession Number"/>
  </order>
</inFulfillmentOf>
<documentationOf>
  <serviceEvent classCode="ACT">
    <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
    <!-- study instance UID -->
    <code code="78814"
      displayName="Positron emission tomography (PET) with concurrently acquired computed
tomography (CT)"
      codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT4"/>
    <effectiveTime value="20060823222400"/>
    <performer typeCode="PRF">
      <templateId root="2.16.840.1.113883.10.20.6.2.1"/>
      <assignedEntity>
        <id extension="121008" root="2.16.840.1.113883.19.5"/>
        <code code="2085R0202X" codeSystem="2.16.840.1.113883.11.19465"
          codeSystemName="NUCC" displayName="Diagnostic Radiology"/>
        <addr nullFlavor="NI"/>
        <telecom nullFlavor="NI"/>
        <assignedPerson>
          <name>
            <given>Matt</given>
            <family>Cure</family>
            <suffix>MD</suffix>
          </name>
        </assignedPerson>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
<relatedDocument typeCode="XFRM">
  <parentDocument>

```

```

<id root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.9"/>
<!-- SOP Instance UID (0008,0018) -->
</parentDocument>
</relatedDocument>
<componentOf>
  <encompassingEncounter>
    <id extension="9937012" root="1.3.6.4.1.4.1.2835.12"/>
    <effectiveTime value="20060828170821"/>
    <encounterParticipant typeCode="ATND">
      <templateId root="2.16.840.1.113883.10.20.6.2.2"/>
      <assignedEntity>
        <id extension="4" root="2.16.840.1.113883.19"/>
        <code code="208D00000X" codeSystem="2.16.840.1.113883.11.19465"
          codeSystemName="NUCC" displayName="General Practice"/>
        <addr nullFlavor="NI"/>
        <telecom nullFlavor="NI"/>
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Fay</given>
            <family>Family</family>
          </name>
        </assignedPerson>
      </assignedEntity>
    </encounterParticipant>
  </encompassingEncounter>
</componentOf>
<component>
  <structuredBody>
    <component>
      <!--
*****
      DICOM Object Catalog Section
*****
-->
      <section classCode="DOCSECT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.6.1.1"/>
        <code code="121181" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
          displayName="DICOM Object Catalog"/>
        <entry>
          <!--
*****
          Study
*****
-->

```

```

<act classCode="ACT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.6"/>
  <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
  <code code="113014" codeSystem="1.2.840.10008.2.16.4"
    codeSystemName="DCM" displayName="Study"/>
  <!--
  *****
  Series and SopInstance UID removed for brevity
  *****
-->
</act>
</entry>
</section>
<!--
*****
End of DICOM Object Catalog Section
*****
-->
</component>
<component>
  <!--
  *****
Social History Section
*****
-->
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.17" extension="2015-08-01"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Social History</title>
  <text> The patient was born female, identifies as male and is currently
    undergoing gender affirming hormone therapy. <table border="1" width="100%"
      cellpadding="0" cellspacing="0">
      <thead>
        <tr>
          <th>Obs</th>
          <th>Value</th>
          <th>Kind</th>
          <th>Jurisdiction</th>
          <th>Date Acquired</th>
        </tr>
      </thead>
      <tbody>
        <tr>
          <td>Gender Identity</td>

```

```

        <td>Identifies as male gender</td>
        <td/>
        <td/>
        <td/>
    </tr>
    <tr>
        <td>Pronouns</td>
        <td>He, Him, His, Himself</td>
        <td/>
        <td/>
        <td/>
    </tr>
    <tr>
        <td>Recorded Sex or Gender</td>
        <td>Female</td>
        <td>Sex Assigned at Birth</td>
        <td>California</td>
        <td>201201011450+0600</td>
    </tr>
</tbody>
</table>
</text>
<entry>
    <!-- Gender Identity -->
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01"/>
        <code code="76691-5" codeSystem="2.16.840.1.113883.6.1"
            displayName="Gender Identity"/>
        <statusCode code="completed"/>
        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT" code="446151000124109"
            displayName="Identifies as male gender"> </value>
    </observation>
</entry>
<entry>
    <!-- Pronouns -->
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.15.2" extension="2022-09-01"/>
        <code code="90778-2" codeSystem="2.16.840.1.113883.6.1"
            displayName="Personal pronouns"/>
        <statusCode code="completed"/>
        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" code="LA29518-0"
            displayName="He, Him, His, Himself"/>
    </observation>

```

```

</entry>
<entry>
  <!-- Recorded Sex or Gender -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.4" extension="2022-09-01"/>
    <code code="99502-7" codeSystem="2.16.840.1.113883.6.1"
      displayName="Recorded sex or gender"/>
    <derivationExpr>Enter whether the infant is male, female, or if the sex
      of the infant is ambiguous, enter "unknown."</derivationExpr>
    <statusCode code="completed"/>
    <value xsi:type="CD" code="F">
      <translation code="F" codeSystem="2.16.840.1.113883.11.19756"
        codeSystemName="International Civil Aviation Organization Sex or Gender"
        displayName="Female"/>
    </value>
    <entryRelationship typeCode="COMP">
      <!-- Jurisdiction -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="77969-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Jurisdiction code"/>
        <statusCode code="completed"/>
        <value xsi:type="CD" nullFlavor="OTH" codeSystem="NP">
          <!-- This may be coded but does not have to be -->
          <originalText>California</originalText>
        </value>
      </observation>
    </entryRelationship>
    <entryRelationship typeCode="COMP">
      <!-- Document Type -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="92183-3" codeSystem="2.16.840.1.113883.6.1"
          displayName="Document type"/>
        <statusCode code="completed"/>
        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" code="71230-7"
          displayName="Birth Certificate"/>
      </observation>
    </entryRelationship>
    <entryRelationship typeCode="COMP">
      <!-- Date of Entry -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="50786-3" codeSystem="2.16.840.1.113883.6.1"
          displayName="Date of entry"/>
        <statusCode code="completed"/>
        <value xsi:type="TS" value="201201011450+0600"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>

```

```

        </observation>
        </entryRelationship>
    </observation>
</entry>
</section>
<!--
*****
End of Social History Section
*****
-->
</component>
<component>
<!--
*****

```

### Reason for study Section

```

*****
-->
<section>
  <code code="121109" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
    displayName="Indications for Procedure"/>
  <title>Indications for Procedure</title>
  <text>Discordant clinical, ECG, and myocardial perfusion SPECT results</text>
</section>
<!--
*****

```

### End of Reason for study Section

```

*****
-->
</component>
<component>
<!--
*****

```

### History Section

```

*****
-->
<section>
  <code code="11329-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="History"/>
  <title>History</title>
  <text>
    <paragraph>
      <caption>History</caption>
      <content ID="Fndng1">History goes here...</content>
    </paragraph>
  </text>

```

```

<entry>
  <!-- History report element (TEXT) -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.6.2.12"/>
    <code code="121060" codeSystem="1.2.840.10008.2.16.4"
      codeSystemName="DCM" displayName="History"/>
    <value xsi:type="ED"> History text </value>
  </observation>
</entry>
<!--

```

\*\*\*\*\*

### Supporting information for Sex for Clinical Use

This is not likely to appear in a PET/CT report  
but is provided to illustrate the use of the  
supporting reference.

\*\*\*\*\*-->

```

<entry>
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <!-- ** Medication Activity (V2) ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.16"
      extension="2014-06-09"/>
    <id root="6C844C75-AA34-411C-B7BD-5E4A9F206E29"/>
    <statusCode code="active"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20120318"/>
    </effectiveTime>
    <doseQuantity value="1"/>
    <consumable>
      <manufacturedProduct classCode="MANU">
        <!-- ** Medication information ** -->
        <templateId root="2.16.840.1.113883.10.20.22.4.23"
          extension="2014-06-09"/>
        <id root="2a620155-9d11-439e-92b3-5d9815ff4ee8"/>
        <manufacturedMaterial>
          <code code="403922"
            displayName="168 HR estradiol 0.00156 MG/HR Transdermal System"
            codeSystem="2.16.840.1.113883.6.88"
            codeSystemName="RxNorm"/>
        </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
</section>
</component>

```

<!--

\*\*\*\*\*

## End of History Section

\*\*\*\*\*

-->

<!--

\*\*\*\*\*

## Imaging Procedure Description Section

\*\*\*\*\*

-->

<component>

<section classCode="DOCSECT" moodCode="EVN">

<templateId root="1.2.840.10008.9.3"/>

<id root="1.2.840.10213.2.62.9940434234785528.11428954534542805"/>

<code code="55111-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"  
displayName="Current Imaging Procedure Description"/>

<title>Imaging Procedure Description</title>

<text>

<table border="1" width="100%" cellpadding="0" cellspacing="0">

<tbody>

<tr>

<td>Sex For Clinical Use</td>

<td>Female</td>

</tr>

<tr>

<td>Imaging Technique</td>

<td>The patient is a transgender male, undergoing hormonal  
treatment. Based on physician instructions, affirmed gender  
creatinine reference ranges were confirmed to be within  
normal values prior to the administration of non-ionic  
iodinated contrast agent.. CT images for attenuation  
correction and anatomic localization followed by PET images  
were obtained..</td>

</tr>

</tbody>

</table>

</text>

<entry>

<procedure moodCode="EVN" classCode="PROC">

<id root="1.2.840.10213.2.62.7044785528.999999999"/>

<code code="78814"

displayName="Positron emission tomography (PET) with concurrently acquired  
computed tomography (CT)"

codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT4"/>

<entryRelationship typeCode="COMP">



```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.15.3"
    extension="2022-09-01"/>
  <code code="99501-9" codeSystem="2.16.840.1.113883.6.1"
    displayName="Sex for clinical use"/>
  <statusCode code="completed"/>
  <value xsi:type="CD" codeSystem="2.16.840.1.113883.4.642.1.983"
    codeSystemName="Sex For Clinical Use" code="female"
    displayName="Female sex for clinical use"> </value>
  <!--
*****
      Supporting Reference for Sex for Clinical Use -
      This is not likely to appear in a PET/CT report
      but is provided to illustrate the use of the
      supporting reference.
*****
-->

  <entryRelationship typeCode="SPRT">
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.122"/>
      <id root="6C844C75-AA34-411C-B7BD-5E4A9F206E29"/>
      <code nullFlavor="OTH" codeSystem="NP"/>
      <statusCode code="completed"/>
    </act>
  </entryRelationship>
</observation>
</entryRelationship>

</procedure>

</entry>
</section>
</component>
<!--
*****
      End of Imaging Procedure Description Section
*****
-->

  <component>
    <!--
*****
      Findings Section
*****
-->
    <!--

```

\*\*\*\*\*

SUV value - Radiologist determines relevant sex at time of  
measurement and adds as DICOM acquisition context

\*\*\*\*\*

-->

```
<section>
  <templateId root="2.16.840.1.113883.10.20.6.1.2"/>
  <code code="121070" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
    displayName="Findings"/>
  <title>Findings</title>
  <text>
    <paragraph>
      <caption>Finding</caption>
      <content ID="Fndng2">Findings narrative goes here...</content>
    </paragraph>
    <paragraph>
      <caption>Standardized uptake value</caption>
      <content ID="Suv2">12g/ml {SUVIbm}</content>
    </paragraph>
    <paragraph>
      <caption>Source of Measurement</caption>
      <content ID="SrceOfMeas2">
        <linkHtml
```

href="http://www.example.org/radiology1.2.840.113619.2.62.994044785528.114289542805/series/1.2.250.1.59.40211.789001276.14556172.67789/instances/1.2.250.1.59.40211.2678810.87991027.899772.2;contentType=application/dicom"

```
      >Coronal</linkHtml>
    </content>
  </paragraph>
</text>
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <!-- Text Observation -->
    <templateId root="2.16.840.1.113883.10.20.6.2.12"/>
    <code code="121071" codeSystem="1.2.840.10008.2.16.4"
      codeSystemName="DCM" displayName="Finding"/>
    <value xsi:type="ED">
      <reference value="#Fndng2"/>
    </value>
    <!-- inferred from measurement -->
    <entryRelationship typeCode="SPRT">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.6.2.14"/>
        <code code="52988006" codeSystem="2.16.840.1.113883.6.96"
```

```

        codeSystemName="SNOMED" displayName="Lesion">
        <originalText>
        <reference value="#Suv2"/>
        </originalText>
    </code>
    <!-- no DICOM attribute -->
    <statusCode code="completed"/>
    <effectiveTime value="20060823223912"/>
    <value xsi:type="PQ" value="12" unit="g/ml{SUVlbm}">
        <translation code="g/ml{SUVlbm}"
            codeSystem="2.16.840.1.113883.6.8" codeSystemName="UCUM"
            codeSystemVersion="1.5"/>
    </value>
    <!--
*****
Second SFCU observation to support SUV interpretation
*****
** -->

    <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.15.3"
                extension="2022-09-01"/>
            <code code="99501-9" codeSystem="2.16.840.1.113883.6.1"
                displayName="Sex for clinical use"/>
            <statusCode code="completed"/>
            <value xsi:type="CD"
                codeSystem="2.16.840.1.113883.4.642.1.983"
                codeSystemName="Sex For Clinical Use" code="male"
                displayName="Male sex for clinical use"> </value>
        </observation>
    </entryRelationship>

    <!-- inferred from image -->
    <entryRelationship typeCode="SUBJ">
        <observation classCode="DGIMG" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.6.2.8"/>
            <!-- (0008,1155) Referenced SOP Instance UID-->
            <id
                root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.3"/>
            <!-- (0008,1150) Referenced SOP Class UID -->
            <code code="1.2.840.10008.5.1.4.1.1.128"
                codeSystem="1.2.840.10008.2.6.1"
                codeSystemName="DCMUID"
                displayName="Positron Emission Tomography Image Storage"> </code>
            <text mediaType="application/dicom">

```

```

        <!-- reference to PET DICOM image -->
        <reference
            value="http://www.example.org/radiology1.2.840.113619.2.62.994044785528.114289542805/series/1.
            2.250.1.59.40211.789001276.14556172.67789/instances/1.2.250.1.59.40211.2678810.87991027.899772
            .2;contentType=application/dicom"
        />
    </text>
    <effectiveTime value="20060823223232"/>
    <!-- Referenced Frames -->
    <entryRelationship typeCode="COMP">
        <observation classCode="ROIBND" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.6.2.10"/>
            <code code="121190"
                codeSystem="1.2.840.10008.2.16.4"
                displayName="Referenced Frames"/>
            <entryRelationship typeCode="COMP">
                <!-- Boundary Observation -->
                <observation classCode="OBS" moodCode="EVN">
                    <templateId root="2.16.840.1.113883.10.20.6.2.11"/>
                    <code code="113036"
                        codeSystem="1.2.840.10008.2.16.4"
                        displayName="Group of Frames for Display"/>
                    <value xsi:type="INT" value="1"/>
                </observation>
            </entryRelationship>
        </observation>
    </entryRelationship>
    <!-- Purpose of Reference -->
    <entryRelationship typeCode="RSON">
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.6.2.9"/>
            <code code="ASSERTION"
                codeSystem="2.16.840.1.113883.5.4"/>
            <value xsi:type="CD" code="121112"
                codeSystem="1.2.840.10008.2.16.4"
                codeSystemName="DCM"
                displayName="Source of Measurement">
                <originalText>
                    <reference value="#SrceOfMeas2"/>
                </originalText>
            </value>
        </observation>
    </entryRelationship>
</observation>

```

```

        </entryRelationship>
      </observation>
    </entryRelationship>
  </observation>
</entry>
</section>
<!--
*****
      End of Findings Section
*****
-->
</component>
<component>
  <!--
*****
      Impressions Section
*****
-->
  <section>
    <code code="121072" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
      displayName="Impressions"/>
    <title>Impressions</title>
    <text>
      <paragraph>
        <caption>Impression</caption>
        <content ID="Fndng3">Impression goes here...</content>
      </paragraph>
    </text>
    <entry>
      <!-- Impression report element (TEXT) -->
      <observation classCode="OBS" moodCode="EVN">
        <!-- Text Observation -->
        <templateId root="2.16.840.1.113883.10.20.6.2.12"/>
        <code code="121073" codeSystem="1.2.840.10008.2.16.4"
          codeSystemName="DCM" displayName="Impression"/>
        <value xsi:type="ED">
          <reference value="#Fndng3"/>
        </value>
      </observation>
    </entry>
    <entry>
      <act moodCode="EVN" classCode="ACT">
        <templateId root="2.16.840.1.113883.10.20.6.2.5"/>
        <!-- Procedure Context template -->
        <code code="78814"

```

```

        displayName="Positron emission tomography (PET) with concurrently acquired computed
tomography (CT)"
        codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT4"/>
        <!-- Note: This code is slightly different than the code used in the header documentationOf
and overrides it, which is what this entry is for. -->
        <effectiveTime value="20060823222400"/>
    </act>
</entry>
</section>
<!--
*****
End of Impressions Section
*****
-->
</component>
</structuredBody>
</component>
</ClinicalDocument>

```