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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
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1 INTRODUCTION

1.1 Outline of gender harmony artifacts in CDA

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.

The Gender Harmony logical model identifies five classes: “gender identity,” “pronouns,” “name to use,” “recorded sex or gender,” and “sex for clinical use.” Because the CDA person name supports name use timeframes, this guide does not specify a template for “name to use.” It includes templates for each of the remaining four classes. It also includes one inherited template used by “sex for clinical use.”

1.2 Guidance on use of gender harmony artifacts in systems

This guide does not define any document or section templates, 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 entries based on three templates (Gender Identity, Pronouns, and Recorded Sex or Gender) 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. Open templates allow HL7 implementers to develop additional structured content not defined within any specific guide. 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.

1.3 Backwards compatibility of GH artifacts

Name to use, as noted above, is not templated, as it is supported by Person Name data type.

Pronouns is a new template.

Sex for Clinical Use is a new template.

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, and all of its constraints are looser, so it is feasible to use both template IDs in a template instance. The most significant difference, and one we hope implementers will find useful, is a value set that addresses gender only, without precoordinated history.

Recorded Sex or Gender represents values that may be captured in existing templates, such as Birth Sex Observation, and possibly in the Patient.administrativeGenderCode, but it does so in a more generic manner. A Birth Sex Observation can be represented as a Recorded Sex or Gender by putting the Birth Sex Observation.code into the element type subentry of Recorded Sex or Gender.

1.4 Design considerations

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. The ballot publication includes a cross-walk table to identify how the logical elements are represented across CDA, FHIR, and HL7 V2.

Another consideration is semantic scope. Three of the templates – gender identity, pronouns, and recorded sex or gender – have patient scope. Their inclusion in a Social History section seems appropriate for anticipated use cases.

Sex for Clinical Use (SFCU) is different. It is designed to contextualize clinical operations. It may constrain the execution of a specific intervention, or it may affect the interpretation of a specific result. The target activity scopes the validity of the observation. The requirement unique to SFCU is to associate the SFCU observation with the appropriate target or 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 section boundaries 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 defined here describes an approach using entryRelationship to establish context specific to an entry, 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. It also requires the use of the Entry Reference template where the SFCU applies to multiple entries.

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 rendered as methodCode or 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 **STATIC**) (CONF:4536-56).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4536-57).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-46) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.1" (CONF:4536-51).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-52).
4. **SHALL** contain exactly one [1..1] **code** (CONF:4536-47).
    a. This code **SHALL** contain exactly one [1..1] **@code**="76691-5" Gender identity (CONF:4536-53).
    b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:4536-54).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-140).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:4536-49).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-58).
7. **MAY** contain exactly one [1..1] **effectiveTime** (CONF:4536-50).
8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHOULD** be selected from ValueSet **Gender Identity Core Concepts** urn:oid:2.16.840.1.113762.1.4.1021.106 **DYNAMIC** 2022-07-20 (CONF:4536-48).

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. This value **MAY** contain zero or one [0..1] **@nullFlavor**, which **SHOULD** be selected from ValueSet **Asked but Unknown and Other** urn:oid:2.16.840.1.113762.1.4.1114.17 **DYNAMIC** (CONF:4536-55).

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)
337910000871105	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: **https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion**			
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

```
<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>
```

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 **STATIC**) (CONF:4536-70).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4536-71).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-59) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.2" (CONF:4536-63).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-64).
4. **SHALL** contain exactly one [1..1] **code** (CONF:4536-60).
    a. This code **SHALL** contain exactly one [1..1] **@code**="90778-2" Personal pronouns – Reported (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:4536-65).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-72).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:4536-62).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-68).
7. **MAY** contain exactly one [1..1] **effectiveTime** (CONF:4536-69).
8. **SHOULD** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **MAY** be selected from ValueSet **Pronouns** urn:oid:2.16.840.1.113883.11.19755 **DYNAMIC** 2022-07-20 (CONF:4536-61).

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

    a. This value **MAY** contain zero or one [0..1] **@nullFlavor**, which **SHOULD** be selected from ValueSet **Asked but Unknown and Other** urn:oid:2.16.840.1.113762.1.4.1114.17 **DYNAMIC** (CONF:4536-67).

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: **http://build.fhir.org/valueset-pronouns.html**			
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, Themself

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:4536-84).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-85).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-86) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.4" (CONF:4536-87).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-88).
4. **SHALL** contain exactly one [1..1] **code**, which **MAY** be selected from ValueSet **Administrative Gender (HL7 V3)** urn:oid:2.16.840.1.113883.1.11.1 (CONF:4536-89).
    a. This code **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:4536-97).

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

b. This code **MAY** contain zero or one [0..1] **originalText** (CONF:4536-90).

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

5. **MAY** contain zero or one [0..1] **derivationExpr** (CONF:4536-141).
6. **MAY** contain zero or one [0..1] **text** (CONF:4536-91).
7. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-92).
8. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:4536-94).

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** with @xsi:type="CE" (CONF:4536-93).
    a. This value **MAY** contain zero or one [0..1] **translation** (ValueSet: **international-civil-aviation-organization-sex-or-gender** urn:oid:2.16.840.1.113883.11.19756) (CONF:4536-95).

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:4536-107) such that it
    a. **SHALL** contain exactly one [1..1] **observation** (CONF:4536-108).
        i. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-110).
        ii. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-111).
        iii. This observation **SHALL** contain exactly one [1..1] **code**="77969-4" Jurisdiction code (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-109).
        iv. This observation **SHALL** contain exactly one [1..1] **statusCode**="complete" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-112).
        v. This observation **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:4536-113).
            1. This value **MAY** contain zero or one [0..1] **originalText** (CONF:4536-114).

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:4536-115) such that it
    a. **SHALL** contain exactly one [1..1] **observation** (CONF:4536-116).
        i. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-117).

ii. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-118).
iii. This observation **SHALL** contain exactly one [1..1] **code**="92183-3" Document type (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-119).
iv. This observation **SHOULD** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-120).
v. This observation **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:4536-121).
1. This value **MAY** contain zero or one [0..1] **originalText** (CONF:4536-122).

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:4536-123) such that it
a. **SHALL** contain exactly one [1..1] **observation** (CONF:4536-124).
i. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-126).
ii. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-127).
iii. This observation **SHALL** contain exactly one [1..1] **code**="50786-3" Date of entry (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-125).
iv. This observation **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS" (CONF:4536-128).

Patient Record 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, put the text label in the root Observation.code.originalText, not here.

13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:4536-130) such that it
a. **SHALL** contain exactly one [1..1] **observation** (CONF:4536-131).
i. This observation **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-132).
ii. This observation **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-133).
iii. This observation **SHALL** contain exactly one [1..1] **code**="184216000" Patient record type (CodeSystem: SNOMED CT urn:oid:2.16.840.1.113883.6.96) (CONF:4536-134).

iv. This observation **SHALL** contain exactly one [1..1] **statusCode**="complete" Complete (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-135).

v. This observation **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHOULD** be selected from ValueSet **Recorded Sex Or Gender Type** urn:oid:2.16.840.1.113883.11.19757 (CONF:4536-136).

1. This value **SHALL** contain zero or one [0..1] **@code** (CONF:4536-143).
2. This value **MAY** contain zero or one [0..1] **originalText** (CONF:4536-144).

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:4536-129).

Table 4: Administrative Gender (HL7 V3)

Value Set: Administrative Gender (HL7 V3) urn:oid:2.16.840.1.113883.1.11.1
(Clinical Focus: The gender of a person used for adminstrative purposes (as opposed to clinical gender)),(Data Element Scope:),(Inclusion Criteria: All codes in the Hl7 V3 AdministrativeGender code system),(Exclusion Criteria:)

This value set was imported on 9/29/2020 with a version of Latest.
Value Set Source: **https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.1/expansion**

Code	Code System	Code System OID	Print Name
F	Administrative Gender	urn:oid:2.16.840.1.113883.5.1	Female
M	Administrative Gender	urn:oid:2.16.840.1.113883.5.1	Male
UN	Administrative Gender	urn:oid:2.16.840.1.113883.5.1	Undifferentiated

Table 5: 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: **http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html**

Code	Code System	Code System OID	Print Name
F	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.642.1.0	Female
M	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.642.1.0	Male
<	International Civil Aviation Organization Sex or Gender	urn:oid:2.16.840.1.113883.4.642.1.0	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>
    <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>
```

```
</observation>
```

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:4536-74).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-75).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-76) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.3" (CONF:4536-77).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-78).
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:4536-79).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-80).
6. **SHALL** contain exactly one [1..1] **statusCode**="complete" Complete (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-81).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:4536-82).
8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet **sex-for-clinical-use** urn:oid:2.16.840.1.113883.4.642.3.982 (CONF:4536-83).
9. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:4536-101) 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:4536-104).
    b. **SHALL** contain exactly one [1..1] Entry Reference (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.122) (CONF:4536-102).

Table 6: 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: **http://build.fhir.org/valueset-sex-for-clinical-use.html**			
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

```
<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 -->
    <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>
```

3 VALUE SETS IN THIS GUIDE

Table 7: Value Sets

Name	OID	URL
Administrative Gender (HL7 V3)	urn:oid:2.16.840.1.113883.1.11.1	https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.1/expansion
Asked but Unknown and Other	urn:oid:2.16.840.1.113762.1.4.1114.17	https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion
Gender Identity Core Concepts	urn:oid:2.16.840.1.113762.1.4.1021.106	N/A
international-civil-aviation-organization-sex-or-gender	urn:oid:2.16.840.1.113883.11.19756	http://build.fhir.org/codesystem-international-civil-aviation-organization-sex-or-gender.html
Pronouns	urn:oid:2.16.840.1.113883.11.19755	http://build.fhir.org/valueset-pronouns.html
Recorded Sex Or Gender Type	urn:oid:2.16.840.1.113883.11.19757	http://terminology.hl7.org/ValueSet/recorded-sex-or-gender-type
sex-for-clinical-use	urn:oid:2.16.840.1.113883.4.642.3.982	http://build.fhir.org/valueset-sex-for-clinical-use.html

4 CODE SYSTEMS IN THIS GUIDE

Table 8: Code Systems

Name	OID
Administrative Gender	urn:oid:2.16.840.1.113883.5.1
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 &amp;amp; Ethnicity - CDC"/>
      <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
        codeSystem="2.16.840.1.113883.6.238" codeSystemName="Race &amp;amp; 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>
      <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"/>
    <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"/>
    <assignedPerson>
      <name>
        <given>Bill</given>
        <family>Roentgen</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</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"/>
    <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, identifes 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>
      </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>
        <!--
**********************************************************************
This Substance Administration is supporting information for Sex for Clinical Use. It
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"/>
            <!--
**************************************************************************
This is the first instance of Sex for Clinical Use. It is a subentry of the PET scan
```

```
procedure for which  it is relevant.
**************************************************************************-->
            <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>
                <!--
**************************************************************************
This is reference points to supporting information for Sex for Clinical Use. It is
the basis on which the SFCU is assigned.
**************************************************************************-->
                <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 narritive goes here...</content>
            </paragraph>
            <paragraph>
              <caption>Standardized uptake value</caption>
              <content ID="Suv2">12g/ml{SUVlbm}</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>
      <!--
**********************************************************************
This Substance Administration is supporting information for Sex for Clinical Use. It
is not likely to appear in a PET/CT report but is provided to illustrate the use of
the supporting reference.
**********************************************************************-->
      <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>
```