- 5. **SHALL** contain exactly one [1..1] **code** (CONF:81-19172).
 - a. This code **SHALL** contain exactly one [1..1] @code="113014" (CONF:81-19173).
 - b. This code **SHALL** contain exactly one [1..1] @codeSystem="1.2.840.10008.2.16.4" (CodeSystem: DCM urn:oid:1.2.840.10008.2.16.4) (CONF:81-26506).

If present, the text element contains the description of the study.

- 6. **MAY** contain zero or one [0..1] **text** (CONF:81-9215).
 - a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:81-15995).
 - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:81-15996).
 - 1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:81-15997).

If present, the effectiveTime contains the time the study was started

- 7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:81-9216).
- 8. SHALL contain at least one [1..*] entryRelationship (CONF:81-9219) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="COMP" Component (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 **STATIC**) (CONF:81-9220).
 - b. **SHALL** contain exactly one [1..1] **Series Act** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.63) (CONF:81-15937).

Figure 224: Study Act Example

3.104Substance Administered Act

[act: identifier urn:oid:2.16.840.1.113883.10.20.22.4.118 (open)]

Table 490: Substance Administered Act Contexts

Contained By:	Contains:
Medication Activity (V2) (optional)	
Immunization Activity (V3) (optional)	

This template represents the administration course in a series. The entryRelationship/sequenceNumber in the containing template shows the order of this particular administration in that medication series.

Table 491: Substance Administered Act Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value		
act (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.118)							
@classCode	11	SHALL		1098- 31500	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = ACT		
@moodCode	11	SHALL		<u>1098-</u> <u>31501</u>	urn:oid:2.16.840.1.113883.5.1 001 (HL7ActMood) = EVN		
templateId	11	SHALL		<u>1098-</u> <u>31502</u>			
@root	11	SHALL		<u>1098-</u> <u>31503</u>	2.16.840.1.113883.10.20.22.4 .118		
id	1*	SHALL		<u>1098-</u> <u>31504</u>			
code	11	SHALL		<u>1098-</u> <u>31506</u>			
@code	11	SHALL		<u>1098-</u> <u>31507</u>	416118004		
@codeSystem	11	SHALL		1098- 31508	urn:oid:2.16.840.1.113883.6.9 6 (SNOMED CT) = 2.16.840.1.113883.6.96		
statusCode	11	SHALL		<u>1098-</u> <u>31505</u>	urn:oid:2.16.840.1.113883.5.1 4 (HL7ActStatus) = completed		
effectiveTime	01	MAY		1098- 31509			

- 1. **SHALL** contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:1098-31500).
- 2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:1098-31501).
- 3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-31502) such that it
 - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.118" (CONF:1098-31503).
- 4. **SHALL** contain at least one [1..*] **id** (CONF:1098-31504).
- 5. **SHALL** contain exactly one [1..1] **code** (CONF:1098-31506).
 - a. This code **SHALL** contain exactly one [1..1] @code="416118004" Administration (CONF:1098-31507).
 - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="**2.16.840.1.113883.6.96" (CodeSystem: SNOMED CT urn:oid:2.16.840.1.113883.6.96) (CONF:1098-31508).
- 6. **SHALL** contain exactly one [1..1] **statusCode=**"completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:1098-31505).

7. MAY contain zero or one [0..1] effectiveTime (CONF:1098-31509).

Figure 225: Substance Administered Act Example

```
<substanceAdministration classCode="SBADM" moodCode="EVN">
    <consumable>
        <code code="43" codeSystem="2.16.840.1.113883.12.292" displayName="Hepatitis B</pre>
Vaccine" codeSystemName="CVX" />
    </consumable>
    <entryRelationship typeCode="COMP">
        <!-- This entryRelationship sequenceNumber indicates this is #2 in the series -->
        <sequenceNumber value="2" />
        <act classCode="ACT" moodCode="EVN">
            <!-- Substance Administered Act Template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.118" />
            <id root="df8908d0-40f2-11e3-aa6e-0800200c9a66" />
            <code code="416118004" displayName="administration"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT" />
            <statusCode code="completed" />
            <effectiveTime value="19991101" />
        </act>
    </entryRelationship>
</substanceAdministration>
```

3.105Substance or Device Allergy - Intolerance Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.24.3.90:2014-06-09 (open)]

Table 492: Substance or Device Allergy - Intolerance Observation (V2) Contexts

Contained By:	Contains:
Health Concern Act (V2) (optional)	Reaction Observation (V2) (optional)
Risk Concern Act (V2) (optional)	Severity Observation (V2) (optional)
	Author Participation (optional)
	Criticality Observation (optional)
	Allergy Status Observation (optional)

This template reflects a discrete observation about a patient's allergy or intolerance to a substance or device. Because it is a discrete observation, it will have a statusCode of "completed". The effectiveTime, also referred to as the 'clinically relevant time' is the time at which the observation holds for the patient. For a provider seeing a patient in the clinic today, observing a history of penicillin allergy that developed five years ago, the effectiveTime is five years ago.

The effectiveTime of the Substance or Device Allergy - Intolerance Observation is the definitive indication of whether or not the underlying allergy/intolerance is resolved. If known to be resolved, then an effectiveTime/high would be present. If the date of resolution is not known, then effectiveTime/high will be present with a nullFlavor of "UNK".