HL7 *aECG* Implementation Guide

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Introduction

The Annotated ECG (aECG) HL7 standard was created in response to the FDA's digital ECG initiative introduced November, 2001. The FDA continues to be concerned about evaluating non-cardiac drugs for negative cardiac effects, like prolonged QT. Before this initiative, sponsors were already submitting ECG findings tabulations (e.g. QT interval measurements) with their applications. However, the FDA could not systematically evaluate the ECG waveforms and measurement locations those findings came from. Most (if not all) ECGs in current trials were collected with paper and not electronically retained. The next logical step for the FDA was to ask for the digital waveforms and measurement locations (annotations) be made available with the application.

A necessary step for submitting the ECG waveforms and annotations to the FDA was to have a standard format for the data. An evaluation of current ECG waveform standards found no existing standards that met all the FDA's needs. Therefore the FDA, sponsors, core laboratories, and device manufactures worked together within HL7 to create a standard to meet the needs.

The aECG standard was created by HL7's Regulated Clinical Research Information Management (RCRIM) in response to the FDA's need. It passed final balloting in January, 2004, and was accepted by ANSI May, 2004. The January, 2004 version is the format the FDA expects to receive all annotated ECGs in. Some early adopters started creating ECGs using an intermediate version that HL7 balloted around April, 2003, but it's not known if or for how long the FDA will accept ECGs in that draft format.

This implementation guide (IG) offers supplemental material for the January, 2004 aECG standard. It does not by itself provide all the information required to fully implement the standard. This IG should be used in conjunction with the HL7 aECG standard as well as the standard's XML schema and example aECG file. Viewing the schema in a graphical presentation tool, such as *XMLSPY*, will help a great deal in understanding the XML structure including which elements and attributes are required or optional, and which datatypes to use. The aECG sample can be viewed using *Internet Explorer* or an XML tool such as *XMLSPY* or *oXygen XML Editor*.

Even though the aECG standard was created in response to the FDA's need to have ECG waveforms and annotations, it does not mean that it can not be used for other purposes. For example, ECG core laboratories may choose to give sponsors the annotated waveforms using this standard as well. The lab may pass extra data to the sponsor that the sponsor would not normally want to pass to the FDA. The standard is quite flexible and is capable of accommodating the additional uses. The IG presents information about the aECG standard independently of any particular use. FDA specific issues are left to an appendix.

Anything in this IG that contradicts the official HL7 standard or FDA guidance should be ignored. The official standard and FDA guidance take precedent over this IG. This IG is written to the best of the authors' understanding of the standard and current FDA guidance.

Glossary

- **aECG** – Annotated ECG. The name given to a file or message conforming to HL7's "Annotated ECG" standard. It contains one or more *series* of ECG waveforms pertaining to a *relative time point* and a set of derived ECG findings for that time point.

- **Annotation** – An observation made on or associated with a *series*. E.g. a P-wave onset, a period of atrial fibrillation, the point at which a drug dosage was administered, etc.

- **CDISC** – Clinical Data Interchange Standards Consortium, an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry.

- **Code** – A computer-interpretable string (mnemonic) who's meaning is defined by a *code system*.

- **Code System** – A set of one or more *codes* with definitions assigned by the code system.

- **Code System UID** – An identifier assigned by HL7 to uniquely identify a *code system*.

- **Digital ECG** – A collection of digital information that contains ECG waveforms represented as sequences of numbers.

- **Digital Electrocardiograph** – A microprocessor-controlled *electrocardiograph* that captures the ECG waveforms using analog-to-digital converters and stores the waveforms as sequences of numbers. It produces *digital ECGs.*

- **Electrocardiograph –** A device that records the electrical activity of the patient's heart by tracing voltage-vs-time waveforms on paper.

- **Electrocardiogram** – Traditionally 12 waveforms (leads) arranged on a piece of paper representing 10 seconds of cardiac activity while the patient is lying on his back at rest. It is the physical record of the patient's cardiac activity produced by an *electrocardiograph*.

- **ECG** – Electrocardiogram.   The term has also been used to mean any set of cardiac waveforms (leads) representing any contiguous period of time.

- **Control Variable** – A special type of *code* (and optional value) describing some aspect of the observation method. E.g., the device settings of an electrocardiograph

- **Lead** – A vector along which the heart's electrical activity is recorded as a waveform.

- **MDC** – *Code system* name given to ISO 11073-10101 (IEEE-1073) Medical Device Communications nomenclature by HL7. Source of the ECG leads, control variables, and annotation codes.

- **Nomenclature** – see *code system*.

- **OID** – Object Identifier. A managed scheme for producing unique identifiers in the form of period-separated-integers assigned in a hierarchical manor much like DNS names are assigned on the Internet. Organizations are assigned a prefix, and the organization is responsible for allocating identifiers using their prefix.

- **Reference Event** – An event defined by a study protocol to which relative time points are anchored. E.g. a meal, a drug dosage, etc.

- **Relative Time point** – A time point relative to the *reference event*. E.g. 30 minutes post dosage.

- **ROI** – Region Of Interest. Used to define a region within an ECG series so an annotation can be associated with it. E.g. the region of interest between the onset and offset of the P-wave can be associated with a P-wave annotation.

- **SDTM** – Study Data Tabulation Model, a CDISC standard that is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA).

- **Series** – Contains one or more *sequence sets* sharing a common frame of reference. Because all sequence values are in the same frame of reference, the values are comparable. E.g. all relative time values are relative to the same point in time, and all voltages within Lead II are from the same pair of electrodes, and the subject is in the same "state".

- **Sequence Set** – A set of *sequences* all having the same length and containing related values. E.g. the 2nd value of a sequence is related to the 2nd value of every other sequence in the set.

- **Sequence** – An ordered list of values sharing a common *code*. E.g. sequence of voltage values with code "LEAD II".

- **Study** – A systematic study of a test article (treatment, drug or device) in one or more human subjects.

- **Time point Event** – Commonly called a "visit", but could also be used as the "element" concept from SDTM. It is a concept in a study protocol that groups a set of *reference events* and *relative time points*, often done during a single patient-investigator encounter, but not necessarily.

- **Trial** – see *study*.

- **UID** – Unique Identifier. May either be an *OID* or *UUID*. Used to uniquely identify an entity in an HL7 message.

- **UUID** – Universally Unique Identifier. An unmanaged scheme for creating unique identifiers using computer algorithms.

- **Vocabulary** – see *code system*.

aECG Parts Explained

The aECG is made up of several parts. Each part is explained in its own section followed by an XML example showing how that part is encoded.

AnnotatedECG *(required)*

Contains the annotated ECG waveforms for a particular relative time point within a clinical trial.

Id

Required: The unique identifier (UID) for this particular AnnotatedECG.

Code

Required: **code** fixed to "93000", **codeSystem** fixed to "2.16.840.1.113883.6.12". This is the code for "Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report" from the CPT-4 coding system. In the future, if different types of AnnotatedECGs need to be distinguishable, this code will be used to differentiate them.

Text

Optional: Free text description of the AnnotatedECG.

effectiveTime

Required: Physiologically relevant time range assigned to the ECG findings derived from the annotated ECG data in the aECG. This time range should span the range of timestamps in the statistical dataset records containing the ECG findings derived from these ECG waveforms.

This effectiveTime may be different from the effectiveTime in the Series. The Series effectiveTime is the time as it was reported by the device that authored the Series. The effectiveTime in the AnnotatedECG is the time used in the trial analysis which may have been adjusted for various reasons.

For example, if 3 ECGs are taken back-to-back to derive a single QT finding, the time assigned to the QT finding might be the middle of the time spanned by the 3 ECGs. If the 1st was taken at 9:27:00, the 2nd at 9:28:00, and the 3rd at 9:29:00, the time assigned to the QT finding might be 9:28:00. This effectiveTime would then be 9:28:00 (center=9:28:00). However, if the time assigned to the QT finding is a "span" of time from 9:27:00 to 9:29:00, this effectiveTime would then show the span (low=9:27:00, high=9:29:00).

This is expressed as an interval of time with a low and high timestamp value. See the discussion on timestamps in the appendix for additional discussion.

confidentialityCode

Optional: The blinding status at the time of the ECG acquisition and analysis. The inclusion of this information will help the regulatory reviewer know how the data was collected and analyzed. As of this guide's publishing, no vocabulary has yet been established for this field. Suggested values are from the CDISC lab model:

- **S** – Blinded to sponsor.
- **I** – Blinded to investigator.
- **B** – Blinded to sponsor and investigator.

- **C** – Custom blinding.

reasonCode

Optional: The reason for making the ECG measurements. As of this guide's publishing, no vocabulary has yet been established for this field. Suggested values are:

- **PER_PROTOCOL** – the protocol specified that a measurement be performed at this point in the trial.

- **NOT_IN_PROTOCOL** – the protocol did not specify that a measurement be performed at this point in the trial. However, a measurement was taken (for unspecified reasons).

- **IN_PROTOCOL_WRONG_EVENT** – the protocol specified that a measurement be performed, but it was performed at the wrong point in the trial.

```
<AnnotatedECG>
  <id root="728989ec-b8bc-49cd-9a5a-30be5ade1db5"/>
  <code code="93000" codeSystem="2.16.840.1.113883.6.12"/>
  <text>Annotated ECG for FDA Review</text>
  <effectiveTime>
    <low value="20020510092700"/>
    <high value="20020510092900"/>
  </effectiveTime>
  <confidentialityCode code="B" codeSystem="" displayName="Blinded
to Sponsor and Investigator"/>
  <reasonCode code="PER_PROTOCOL" codeSystem=""/>
</AnnotatedECG>
```

ClinicalTrialProtocol *(optional)*

Contains the identifying information about the protocol used to conduct the trial.

Id

Required: The unique identifier for the protocol used to define the trial. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended that the sponsor assign a unique OID to every new protocol. This OID would go into the *root* part of the ID. The traditional protocol identifier will go into the *extension*. If the protocol defines a set of codes used to name the treatment groups, time point events, reference events, and relative time points, this OID will be used as the coding system identifier.

Title

Optional: The name of the protocol.

```
<clinicalTrialProtocol>
   <id root="2.16.840.1.113883.3.2" extension="PUK-123-PROT-A"/>
   <title>Cardiac Safety Protocol for Compound PUK-123</title>
</clinicalTrialProtocol>
```

ClinicalTrial *(required)*

Contains the identifying information about the trial.

Id

Required: The unique identifier for the trial. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended that the sponsor assign a unique OID to every trial. This OID would go into the *root* part of the ID. The traditional trial identifier will go into the *extension*.

Title

Optional: The name of the trial.

activityTime

Optional: The starting and ending dates of the trial. This helps identify the particular trial, much like a birth date helps identify a particular patient. If the start date is known, but the end date is not known, just include *low*. If the end date is known but the start date is not, just include *high*.

```
<clinicalTrial>
   <id root="2.16.840.1.113883.3.4" extension="PUK-123-TRL-1"/>
   <title>Cardiac Safety Trial 1 for Compound PUK-123</title>
   <activityTime>
      <low value="20010509"/>
      <high value="20020316"/>
   </activityTime>
</clinicalTrial>
```

ClinicalTrial Author *(optional)*

Identifies the sponsoring organization of the clinical trial which is considered the "author" of the trial.

ClinicalTrialSponsor

SponsorOrganization

id

Optional: The unique identifier for the sponsoring organization. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended that the sponsor obtain an OID "root" for its organization. This OID "root" will be used as a prefix for all other OIDs it creates. This OID "root" should be put into the *root* part of the ID. If the sponsor has another more common and well-known identifier, that would go into the *extension*.

Name

Optional: The name of the sponsoring organization.

```
<author>
  <clinicalTrialSponsor>
    <sponsorOrganization>
      <id root="2.16.840.1.113883.3"/>
      <name>ABC Drug Company</name>
    </sponsorOrganization>
  </clinicalTrialSponsor>
</author>
```

ClinicalTrial Location *(optional)*

Identifies the trial site where the ECG waveforms were acquired from the subject.

TrialSite

id

Required: The unique identifier for the trial site. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended at that sponsor (or its vendor) assign a unique OID to every trial site. This OID will go into the *root* part of the ID. The traditional identifier will go into the *extension*.

Location

name

Optional: The name of the site.

Addr

Optional: The address of the site. See the XML schema for a complete listing of fields available for specifying an address.

```
<location>
   <trialSite>
      <id root="2.16.840.1.113883.3.5" extension="SITE_1"/>
      <location>
         <name>1st Clinic of Milwaukee</name>
         <addr>
            <city>Milwaukee</city>
            <state>WI</state>
            <country>USA</country>
         </addr>
      </location>
   </trialSite>
</location>
```

ClinicalTrial ResponsibleParty *(optional)*

Identifies the trial investigator responsible for the acquisition of the ECG waveforms at the trial site.

TrialInvestigator

id

Required: The unique identifier for the investigator. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended at that sponsor (or its vendor) assign a unique OID to every investigator. This OID will go into the *root* part of the ID. The traditional identifier will go into the *extension*.

InvestigatorPerson

name

Optional: The name of the investigator. See the XML schema for a listing of fields for specifying a person's name.

```
<responsibleParty>
  <trialInvestigator>
    <id root="2.16.840.1.113883.3.51" extension="INV_13"/>
    <investigatorPerson>
      <name>
        <family>Smith</family>
        <given>John</given>
        <prefix>Dr.</prefix>
        <suffix>MD</suffix>
      </name>
    </investigatorPerson>
  </trialInvestigator>
</responsibleParty>
```

Subject *(required)*

Identifies the subject from which the ECG waveforms were obtained.

TrialSubject *(required)*

id

Required: The unique identifier for the subject. Composed of a **root** and optional **extension**. The root must be included, and is a UID. The optional **extension** may be anything. The combination of the **root** and **extension** must be universally unique.

It is highly recommended at that sponsor (or its vendor) assign a unique OID to every subject. This OID will go into the *root* part of the ID. The traditional identifier will go into the *extension*.

Code

Optional: The role the subject was in at the time of the ECG waveform collection. As of this guide's publishing, HL7 had defined a vocabulary for this called "ResearchSubjectRoleBasis", UID=" 2.16.840.1.113883.5.111", but does not have any defined codes within it. Suggested values are:

- **SCREENING** – the subject was being screened for participation in the trial but had not yet been enrolled.
- **ENROLLED** – the subject was enrolled in the trial.

SubjectDemographicPerson *(optional)*

name

Optional: The name of the subject. See the XML schema for a listing of fields for specifying a person's name. Often, just the subject's initials are used. In this case, just put the initials between the <name></name> tags without further detail (e.g. family name, given name, etc.). See the example below.

administrativeGenderCode

Optional: The subject's gender. Codes for this field come from HL7's **AdministrativeGender** vocabulary (codeSystem id is "2.16.840.1.113883.5.1"). The following codes are defined:

- **F** – Female
- **M** – Male
- **UN** – Undifferentiated

birthTime

Optional: The subject's date of birth.

raceCode

Optional: The subject's race. Codes for this field come from HL7's **Race** vocabulary (codeSystem id is "2.16.840.1.113883.5.104"). Some of the defined codes are listed below. See official HL7 documentation for a complete listing.

- **1002-5** – RaceNativeAmerican

- **2028-9** – RaceAsian

- **2054-5** – RaceBlackOrAfricanAmerican

- **2076-8** – RaceHawaiianOrPacificIsland

- **2106-3** – RaceWhite

- **2131-1** – Other Race

```
<subject>
  <trialSubject>
    <id root="2.16.840.1.113883.3.55" extension="SUBJ_1"/>
    <code code="ENROLLED" codeSystem="2.16.840.1.113883.5.111"/>
    <subjectDemographicPerson>
      <name>BDB</name>
      <administrativeGenderCode code="M"
        codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19530508"/>
      <raceCode code="2106-3"
        codeSystem="2.16.840.1.113883.5.104"/>
    </subjectDemographicPerson>
  </trialSubject>
</subject>
```

SubjectAssignment *(required)*

This represents the "act" of associating a subject to a trial.

SubjectAssignment Definition *(optional)*

This defines the subject's association with a trial by naming the treatment group he's assigned to.

TreatmentGroupAssignment

This identifies a group of subjects that went through the trial in the same way. In other words, all subjects in the group got the same drug dosages in the same order. This concept is similar to the CDISC SDTM *arm* concept.

Code

Required: The protocol or trial-specific code identifying the treatment group the subject is a member of. If it is a trail-specific code, the codeSystem identifier would name the trial. For example, if the sponsor assigns the UID "2.16.840.1.113883.3.5" to the trial, this UID would be named as the codeSystem. Likewise, if the code is protocol-specific, the codeSystem identifier would name the protocol. For example, if the sponsor assigns the UID "2.16.840.1.113883.3.1" to the protocol, this UID would be named as the codeSystem.

```
<subjectAssignment>
   <subject> ... </subject>
   <definition>
      <treatmentGroupAssignment>
         <code code="GRP_003" codeSystem="2.16.840.1.113883.3.1"/>
      </treatmentGroupAssignment>
   </definition>
   <componentOf>
      <clinicalTrial> ... </clinicalTrial>
   </componentOf>
</subjectAssignment>
```

TimepointEvent *(required)*

The time point or study event during which the ECG waveforms were collected. It is commonly referred to as a "visit" but can also represent the "element" concept from CDISC's SDTM standard.

Code

Optional: This is the code naming the time point event. This could be the visit number, study day, etc. The set of time point event codes is usually defined by the protocol. Therefore, the codeSystem UID usually names the protocol.

effectiveTime

Optional: The time or range of time this time point event occurred.

reasonCode

Optional: The reason for the event. As of this guide's publishing, no vocabulary has been formally established for these codes. Suggested values are from the CDISC lab model VisitType field:

- **S** – scheduled; this was a planned visit according to the protocol.
- **U** – unscheduled; this visit was not planned.

TimepointEvent Performer *(optional)*

The person primarily responsible for this time point event (e.g. subject's visit), other than the trial site investigator (named elsewhere in the AnnotatedECG).

StudyEventPerformer *(optional)*

id

Optional: The unique identifier for this person. Composed of a **root** and optional **extension**. The root must be included, and is a UID.

StudyEventPerformer AssignedPerson

name

Optional: The name of this person.

```
<timepointEvent>
  <code code="VISIT_2" codeSystem="2.16.840.1.113883.3.1"/>
  <effectiveTime>
     <low value="20020509100700"/>
     <high value="20020509134600"/>
  </effectiveTime>
  <reasonCode code="SCHEDULED" codeSystem=""/>
  <performer>
     <studyEventPerformer>
        <id root="2.16.840.1.113883.3.5" extension="TECH_1"/>
        <assignedPerson>
           <name>Julie Tech</name>
```

```
                  </assignedPerson>
              </studyEventPerformer>
          </performer>
          <componentOf>
              <subjectAssignment> ... </subjectAssignment>
          </componentOf>
      </timepointEvent>
```

AnnotatedECG Definition *(optional)*

This identifies the particular ECG assessment for which these ECG waveforms were collected.

RelativeTimepoint

This identifies the time point relative to a reference event. For example, if the protocol says an ECG assessment should be made 30 minutes after the 1st dosage, this time point would identify the "30 minutes post dosage" time point.

Code

Required: The code for this relative time point. This code is most likely defined by the protocol. Therefore, the codeSystem UID should name the protocol. For example, if the protocol UID is "16.840.1.113883.3.1", and the time point is "30 minutes post dosage" with the code "POST_DOSAGE_30", then the XML would like this:

```
<code code="POST_DOSAGE_30" codeSystem="16.840.1.113883.3.1"/>
```

pauseQuantity

Optional: This is the time delay between the ReferenceEvent and RelatativeTimepoint. For example, if the reference event was a dosage, and the relative time point was "30 minutes post dosage", then the pause quantity would be 30 minutes.

ProtocolTimepointEvent

This identifies the time point event (e.g. "visit" or SDTM "element") defined in the protocol. This is almost always the same as the TimepointEvent (the actual time point event of the ECG assessment).

Code

Required: This is the code naming the time point event as defined in the protocol. This could be the visit number, study day, etc. The codeSystem UID usually names the protocol defining this code.

ReferenceEvent

This identifies the reference or benchmark event for the ECG assessment within the time point event (e.g. "visit" or "element"). This could be a dosing, meal, exercise, etc.

code

Required: This is the code naming the reference event. This could be a dosing, meal, exercise, etc. The reference event codes are most likely defined by the protocol, so the codeSystem UID usually names the protocol.

```
<definition>
  <relativeTimepoint>
   <code code="POST_DOSAGE_30" codeSystem="16.840.1.113883.3.1"/>
     <componentOf>
        <pauseQuantity value="1800" unit="s"/>
        <protocolTimepointEvent>
           <code code="VISIT_2" codeSystem="16.840.1.113883.3.1"/>
           <component>
              <referenceEvent>
```

```
                        <code code="DOSAGE_1"
                        codeSystem="16.840.1.113883.3.1"/>
                    </referenceEvent>
                </component>
            </protocolTimepointEvent>
        </componentOf>
    </relativeTimepoint>
</definition>
```

AnnotatedECG Location *(optional)*

If the ECG waveforms were acquired in a location other than the recognized trial site (specified elsewhere in the schema), this is where the name and ID of the actual collection location can be recorded.

TestingSite

id

Optional: The unique identifier for the ECG waveform collection site if different from the trial site. Composed of a **root** and optional **extension**.

Location *(optional)*

name

Optional: The name of the collection site.

Addr

Optional: The address of the collection site. See the schema for a complete listing of elements that can be used to specify an address.

```
<location>
   <testingSite>
      <id root="2.16.840.1.113883.3.5" extension="SITE_43"/>
      <location>
         <name>ECG Collection Site of 1st Clinic</name>
         <addr>
            <city>Milwaukee</city>
            <state>WI</state>
            <country>USA</country>
         </addr>
      </location>
   </testingSite>
</location>
```

AnnotatedECG ControlVariable *(optional)*

Control variables capture related information about the subject or general ECG collection conditions. For example, if the subject's age needs to be recorded independently of the date of birth recorded elsewhere, this can be captured as a control variable. Another example might be the subject's fasting status.

RelatedObservation

code

Optional: The code for the related observation. For example, if the subject's age is captured, the LOINC code "21612-7" can be used for "Reported Age".

Text

Optional: The observation. This element can be used when the observation is not a simple quantity that can be put into the value element.

Value

Optional: The observed value. For example, if the subject's age is observed, this would contain the age value.

RelatedObservation Author

The author of the related observation. The author can either be a person or a device.

AssignedEntity

id

Optional: The unique ID of the observation author. This is the ID assigned by the RepresentedAuthoringOrganization". For example, if the authoring organization is the trial site, this would be ID assigned by that site.

AssignedAuthorType

AssignedPerson

name

Optional: The name of the person who authored the observation.

AssignedDevice

id

Optional: The unique ID of the device that authored the observation.

code

Optional: The type of device. At the time of this guide's publishing, no formal vocabulary had been established for this code.

manufacturerModelName

Optional: The model name of the device.

softwareName

Optional: The name and version of software running in the authoring device.

PlayedManufacturedDevice

ManufacturingOrganization

id

Optional: The unique ID of the authoring device's manufacturer.

Name

Optional: The name of the authoring device's manufacturer.

RepresentedAuthoringOrganization

The organization responsible for the person or device that authored the observation.

id

Optional: The unique ID of the organization. This is an ID that would be globally known outside of the organization's role in the trial.

Name

Optional: The name of the organization.

Identification

id

Optional: The role-specific ID of the organization. This is mostly like an ID assigned by the trial or the sponsoring organization.

```xml
<controlVariable>
  <relatedObservation>
     <code code="21612-7" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Reported Age"/>
     <value xsi:type="PQ" value="34" unit="a"/>
     <author>
        <assignedEntity>
           <id root="2.16.840.1.113883.3.5" extension="TECH_23"/>
           <assignedAuthorType>
              <assignedPerson>
                 <name>JMK</name>
              </assignedPerson>
           </assignedAuthorType>
           <representedAuthoringOrganization>
              <name>1st Clinic of Milwaukee</name>
              <identification>
```

```
                <id root="2.16.840.1.113883.3.5" extension="SITE_1"/>
            </identification>
          </representedAuthoringOrganization>
        </assignedEntity>
      </author>
    </relatedObservation>
  </controlVariable>
```

AnnotatedECG PertainsTo *(optional)*

Captures a pertinent comment made by the subject that may have some relation to the captured ECG waveforms. For example, the subject may indicate that he felt dizzy 2 minutes prior to taking the ECG.

SubjectFindingComment

code

Optional: The code identifying the type of comment made. If the comment is not coded (e.g. free text), then no code is necessary.

Text

Optional: The comment itself it if can't be encoded in the value element.

Value

Optional: The value of the comment. Most likely used when the comment is coded.

Author *(optional)*

The person or device that recorded the comment from the subject. See "AnnotatedECG ControlVariable" author for details.

```
<pertainsTo>
  <subjectFindingComment>
     <text>Subject felt dizzy 2 minutes prior to ECG</text>
  </subjectFindingComment>
</pertainsTo>
```

AnnotatedECG Component *(optional)*

The component parts of the aECG. These are the waveforms and annotations. Even though the XML schema says this is an optional part of the aECG message, the message is not very useful without at least one series containing at least one waveform.

Series

A series contains all the sequences, regions of interest, and annotations sharing a common frame of reference. All physical quantities having the same code must all be comparable. For example, if the series contains 2 different voltage sequences for lead II, the voltages in those sequences must be comparable and come from the same set of electrodes. If the electrodes were changed (and possibly moved), or if additional filtering were used to record one of the sequences, those sequences must appear in different series.

Typically a series will contain all the waveforms and annotations for a single ECG. If multiple ECGs are contained within a single aECG file, a different series is used for each.

A series can be derived from another series. For example, a series containing representative beat waveforms is algorithmically derived from a rhythm series. Or, a series containing waveforms with special filtering applied can be algorithmically derived from the "raw" rhythm waveforms.

Id

Optional: The unique ID of the series. This is typically assigned by the ECG waveform collection device or the ECG management system that exported the aECG. This may be in the form of an OID or UUID, but is typically a UUID.

Code

Required: The code identifying the type of series. Currently there are 2 choices from the HL7 ActCode vocabulary (OID = 2.16.840.1.113883.5.4):

- **RHYTHM** – the series contains rhythm waveforms. These are the waveforms collected by the device. The voltage samples are related to each other in real time (wall time).

- **REPRESENTATIVE_BEAT** – the series contains the waveforms of a representative beat derived from a series of rhythm waveforms. The voltage samples are related to each other in time that's relative to the beginning of the cardiac cycle, not real time.

effectiveTime

Required: Physiologically relevant time range assigned to the ECG waveforms contained within the series. This is typically referred to as the "acquisition time" which is determined by the device that collected the waveforms. If the device just recorded the beginning of acquisition, the time would go into the **low** part of the interval. If the device just recorded time when the data collection was finished, the time would go into the **high** part of the interval.

```
<component>
  <series>
    <id root="b65deea0-078e-11d9-9669-0800200c9a66"/>
    <code code="RHYTHM" codeSystem="2.16.840.1.113883.5.4"/>
    <effectiveTime>
        <low value="20021122091000"
        <high value="20021122091010"
```

```
            </effectiveTime>
        </series>
    </component>
```

```
            </effectiveTime>
```

Series SeriesAuthor *(optional)*

This describes the device that "authored" (recorded) the series waveforms. This would typically describe an electrocardiograph or Holter recorder.

Id

Optional: The unique identifier of the device in its role as the waveform author in this clinical trial. This could be assigned by the investigator, the investigator's healthcare organization, a CRO, or even the trial's sponsor.

The id has a root and extension part. The root must be a UID, and the optional extension can be anything. However, it is highly recommended that the traditional identifier be put into the extension.

manufacturedSeriesDevice *(required)*

id

Optional: The unique identifier of the device, independent of its role (i.e. independent of trial). This would typically be the serial number assigned by the device manufacturer. For example, the root part of the id could be the OID identifying the manufacturing organization, and the extension could be the serial number.

Code

Optional: Identifies the type of device. As of this guide's publishing, there has been no vocabulary established for coding device types. Suggested codes might be:

- **12LEAD_ELECTROCARDIOGRAPH**
- **12LEAD_HOLTER**

manufacturerModelName

Optional: Model name of the device.

softwareName

Optional: Name and/or version of the software in the device.

manufacturerOrganization *(optional)*

id

Optional: Unique identifier of the organization that manufactured the device. This would typically be in the form of an OID.

Name

Optional: Name of the organization that manufactured the device.

```
<author>
  <seriesAuthor>
    <id root="2.16.840.1.113883.3.5" extension="45"/>
    <manufacturedSeriesDevice>
      <id root="1.3.6.1.4.1.57054" extension="SN234-AR9-102993"/>
      <code code="12LEAD_ELECTROCARDIOGRAPH" codeSystem=""/>
```

```
            <manufacturerModelName>Electrograph 250</manufacturerModelName>
            <softwareName>Rx 5.3</softwareName>
        </manufacturedSeriesDevice>
        <manufacturerOrganization>
            <id root="1.3.6.1.4.1.57054"/>
            <name>ECG Devices By Smith, Inc.</name>
        </manufacturerOrganization>
    </seriesAuthor>
</author>
```

Series SecondaryPerformer *(optional)*

This describes the technician(s) operating the device that captured the ECG waveforms.

functionCode

Optional: Describes the function the technician was performing. For example, there might be 2 separate technicians involved in making a Holter recording, the technician that performed the recorder hookup, and the technician that performed the waveform analysis and produced a summary report of the Holter test. As of this guide's publishing, there has been no vocabulary established for secondary performer functions in the context of a clinical trial. Suggested codes might be:

- **HOLTER_HOOKUP_TECH**
- **HOLTER_ANALYST**
- **ELECTROCARDIOGRAPH_TECH**

time

Optional: The time or time period during which the technician was performing the indicated function for this series.

seriesPerformer *(required)*

id

Optional: The role-specific unique identifier of the secondary performer. This is the identifier assigned to this technician in his role within the trial. This could be an id assigned by the investigator, the technician's employer, the CRO, or sponsor.

assignedPerson *(optional)*

name

Optional: The name of the technician. This can be a simple as the technician's initials, or the full name including first, middle, last, prefix, suffix, etc.

```xml
<secondaryPerformer>
  <functionCode code="ELECTROCARDIOGRAPH_TECH" codeSystem=""/>
  <time>
    <low value="20021122091000"
    <high value="20021122091010"
  </time>
  <seriesPerformer>
    <id root="2.16.840.1.113883.3.4" extension="TECH-221"/>
    <assignedPerson>
      <name>KAB</name>
    </assignedPerson>
  </seriesPerformer>
</secondaryPerformer>
```

Series Support *(optional)*

A series can be derived from another series, usually by applying an algorithm to transform the waveform data into another form for a particular type of analysis. If a series is derived from part of another series, this supporting region of interest (ROI) tells what part of the parent series it was derived from. If the derivative series was from the entire parent, no supporting ROI is necessary to specify a subset of the parent.

An example might be of having 3 minutes of rhythm waveforms from which representative beats are derived. It doesn't often make sense to derive representative beats from long periods of time, so there may be several representative beats derived from short segments of the parent rhythm waveforms. If the representative beats were derived for every 30 seconds, there would be 6 derived series, and each would have a supporting ROI to say which part of the parent they were derived from.

supportingROI

code

Required: Specifies if the ROI is fully specified or partially specified by its component boundaries.

A fully specified ROI has all the boundaries defining the parts of all the named sequence codes considered part of the region. Any sequence codes not having boundaries are not part of the region. For example, a series for a 12-lead ECG will have 13 sequence codes, one for time and 12 for the 12 leads. If waveforms from the 1st 30 seconds of leads II, V2, and V5 were used in the derivative series, the region would have 4 boundaries: a time boundary for the 1st 30 seconds, and unvalued boundaries for leads II, V2, and V5. All other unnamed leads would not be part of the region.

A partially specified ROI includes all named sequences by default unless a boundary specifies otherwise. For example, a series for a 12-lead ECG will have 13 sequence codes, one for time and 12 for the 12 leads. If all the waveforms from the 1st 30 seconds were used in the derivative series, the region would have 1 boundary: a time boundary for the 1st 30 seconds. Because no boundaries are given for the leads, all the leads are considered part of the region.

Codes for this come from the HL7 V3 ActCode vocabulary, OID=" 2.16.840.1.113883.5.4". Allowed codes are:

- **ROIPS** – Partially specified region of interest. A partially specified bounded Region of Interest (ROI) specifies a ROI in which at least all values in the dimensions specified by the boundary criteria participate. For example, if an episode of ventricular fibrillations (Vfib) is observed, it usually doesn't make sense to exclude any ECG leads from the observation and the partially specified ROI would contain only one boundary for time indicating the time interval where Vfib was observed.

- **ROIFS** – Fully specified region of interest. A fully specified bounded Region of Interest (ROI) delineates a ROI in which only those dimensions participate that are specified by boundary criteria, whereas all other dimensions are excluded. For example a ROI to mark an episode of "ST elevation" in a subset of the ECG leads V2, V3, and V4 would include 4 boundaries, one each for time, V2, V3, and V4.

Boundary

A boundary specifies the part of a series dimension (sequence code) included in the region. For example, if the region includes the 1st 30 seconds of waveforms, a boundary will have the code for time and a value indicating the time interval. The code used must be a code that exists in the

series. It is not allowed, for example, to use a code for absolute time in the series data, but a code for relative time in a boundary.

If the entire named dimension is part of the region, for example all voltage values in lead II, then no value or range of values is necessary. Values are only necessary if a subset of the dimension is included in the region.

Code

Required: The code naming a dimension of the series. Must be a code from the series.

Value

Optional: The value, range of values, or list of values included from the dimension.

The following example shows a fully specified ROI for the first 30 seconds of a series using relative time. The ROI includes all of leads II, V2, and V5.

```xml
<support>
   <supportingROI>
      <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
      <component>
         <boundary>
            <code code="TIME_RELATIVE" codeSystem="2.16.840.1.113883.5.4"/>
            <value xsi:type="IVL_PQ">
               <low value="0" unit="ms"/>
               <high value="30000" unit="ms"/>
            </value>
         </boundary>
      </component>
      <component>
         <boundary>
            <code code="MDC_ECG_LEAD_II" codeSystem="2.16.840.1.113883.6.24"/>
         </boundary>
      </component>
      <component>
         <boundary>
            <code code="MDC_ECG_LEAD_V2" codeSystem="2.16.840.1.113883.6.24"/>
         </boundary>
      </component>
      <component>
         <boundary>
            <code code="MDC_ECG_LEAD_V5" codeSystem="2.16.840.1.113883.6.24"/>
         </boundary>
      </component>
   </supportingROI>
</support>
```

Series ControlVariable *(optional)*

Describes some aspect about the conditions under which the series was recorded or derived. For example, if the series was recorded on an electrocardiograph that used a low-pass filter cutoff of 150 Hz, then a control variable could be used to indicate that fact. If the series was derived by filtering out frequencies above 40 Hz found in the parent series, then a control variable could be used to indicate that.

Note that control variables can be nested so additional levels of details about the control variable can be described. For example, a filter may have several key parameters that are important to describe and therefore must be composed of multiple variables and values.

Code

Required: Indicates the control variable. The MDC vocabulary (OID="2.16.840.1.113883.6.24") includes most of the control variables likely to be used to describe devices used to record ECG waveforms.

Value

Optional: The value of the control variable. For example, if the control variable is for the cutoff frequency of a filter, the value would indicate the frequency.

```
<controlVariable>
  <controlVariable>
    <code code="MDC_ECG_CTL_VBL_ATTR_FILTER_LOW_PASS"
codeSystem="2.16.840.1.113883.6.24"/>
    <component>
      <controlVariable>
        <code code="MDC_ECG_CTL_VBL_FILTER_CUTOFF_FREQ"
codeSystem="2.16.840.1.113883.6.24"/>
        <value xsi:type="PQ" value="150" unit="Hz"/>
      </controlVariable>
    </component>
  </controlVariable>
</controlVariable>
```

SequenceSet *(required)*

Groups 2 or more related sequences together. Each sequence must have the same length. The first value of each sequence is related to the first value of every other sequence. The second value of each sequence is related to the second value of every other sequence, and so on. A sequence set can be thought of as a table where every sequence is a column in the table, and the rows indicate which values are related.

For example, if an electrocardiograph records a 12-lead ECG by recording all leads simultaneously, then the ECG series would be made up of a single sequence set having a time sequence and 12 lead sequences. If, on the other hand, the electrocardiograph only records 3 leads at a time because it has a limited number of A/D channels, the ECG series would be made up of 4 sequence sets each having a time sequence and 3 lead sequences.

SquenceSet ControlVariable *(optional)*

Describes some aspect about the conditions under which the sequence set was recorded. Normally all the control variables would be put at the series level. However, if this sequence set was different in some way (but not different enough to warrant a new series), control variables at the sequence set level can be used. See the series control variable discussion for additional details and examples.

Sequence *(required)*

A sequence is an ordered list of values having a common code (or dimension). The sequence values are associated with other sequence values within a sequence set. For example, a 12-lead ECG series will contain a sequence for the timestamps at which the electrocardiograph sampled the lead voltages, and 12 other sequences containing the voltages measured at those times.

Code

Required: Names the dimension, or type, of values in the sequence.

Codes for time sequences come from the HL7 ActCode vocabulary (OID=" 2.16.840.1.113883.5.4"). Allowed codes are:

- **TIME_ABSOLUTE** – A sequence of values in the "absolute" time domain. This is the same time domain that all HL7 timestamps use. It is time as measured by the Gregorian calendar.

- **TIME_RELATIVE** – A sequence of values in a "relative" time domain. The time is measured relative to the earliest effective time in the series containing this sequence.

Codes for voltage sequences come from the MDC vocabulary (OID="2.16.840.1.113883.6.24"). A few examples are:

- **MDC_ECG_LEAD_I**
- **MDC_ECG_LEAD_II**
- **MDC_ECG_LEAD_III**
- **MDC_ECG_LEAD_AVR**
- **MDC_ECG_LEAD_AVL**
- **MDC_ECG_LEAD_AVF**
- **MDC_ECG_LEAD_V1**
- **MDC_ECG_LEAD_V2**
- **MDC_ECG_LEAD_V3**
- **MDC_ECG_LEAD_V4**
- **MDC_ECG_LEAD_V5**
- **MDC_ECG_LEAD_V6**

value

Required: The list of values in the sequence. The list of values can either be generated from a simple algorithm, or can be explicitly enumerated.

HL7 has the collection datatype **GLIST<>** for a "generated list" of values using an algorithm. Since most ECG devices use a periodic sampling frequency, this is most useful for generating the sequence of times at which voltages were sampled.

HL7 has another collection datatype called **SLIST<>** for "sampled list". This is used to enumerate all the voltages in the ECG waveform. This datatype has a couple other useful attributes. A common scale factor and offset can be factored out of the sequence of values. This allows for the "raw" integer values to be encoded in the HL7 message for more efficient

storage. The scale factor and offset are applied by the consumer of the message to convert the values into true physical quantities.

Sequence ControlVariable *(optional)*

Describes some aspect about the conditions under which the sequence was recorded. Normally all the control variables would be put at the series level. However, if this sequence was different in some way (but not different enough to warrant a new series), control variables at the sequence level can be used. See the series control variable discussion for additional details and examples.

The following example shows a very simple case of a 5 sample, 2 lead ECG acquired by a 500 Hz sampling device and having a 5 µV amplitude resolution.

```
<component>
  <sequenceSet>
    <component>
      <sequence>
        <code code="TIME_ABSOLUTE" codeSystem="2.16.840.1.113883.5.4"/>
        <value xsi:type="GLIST_TS">
          <head value="20021122091000.000"/>
          <increment value="0.002" unit="s"/>
        </value>
      </sequence>
    </component>
    <component>
      <sequence>
        <code code="MDC_ECG_LEAD_I" codeSystem="2.16.840.1.113883.6.24"/>
        <value xsi:type="SLIST_PQ">
          <origin value="0" unit="uV"/>
          <scale value="5" unit="uV"/>
          <digits>1 2 3 4 5</digits>
        </value>
      </sequence>
    </component>
    <component>
      <sequence>
        <code code="MDC_ECG_LEAD_II" codeSystem="2.16.840.1.113883.6.24"/>
        <value xsi:type="SLIST_PQ">
          <origin value="0" unit="uV"/>
          <scale value="5" unit="uV"/>
          <digits>10 11 12 13 14</digits>
        </value>
      </sequence>
    </component>
  </sequenceSet>
```

Series SubjectOf *(optional)*

The series is the "subject of" annotation sets.

AnnotationSet *(required)*

Annotations are grouped in annotation sets. Each set of annotations has a single author who created the annotations together at one time. For example, there could be one set of annotations authored by the electrocardiograph that recorded the waveforms. Another set of annotation could be created by an initial review of an ECG core laboratory technician. And yet another set could be created by a cardiologist checking the work of the technician.

Code

Optional: The type of annotation set. As of this guide's publishing, no vocabulary has been established for this code. It's not clear if different types of annotation sets need to be distinguishable. If they do, it might be necessary to code one set as "automatic" annotations authored by the recording device. Other set types might be protocol or SOP specific depending on the workflow and how many people and how many times annotations might be placed on an ECG.

activityTime

Optional: The point in time or range of time during which the annotation set was created. If the recoding device authored the annotations, this time will closely match the series effective time. If a core laboratory technician authored the annotations, the time might be a few minutes, hours, or even days after the ECG was acquired.

methodCode

Optional: The method used to create the annotations. As of this guide's publishing, no vocabulary has been established for annotation methods.

AnnotationSet Author *(optional)*

This describes the device or person what authored the annotations. See AnnotatedEcg ControlVariable Author for details and an example.

AnnotationSet ControlVariable *(optional)*

Describes the conditions under which the annotations were created. If the annotations were created automatically by computer algorithms, control variables describing the algorithm's configuration might be important. For example, if the algorithm detects and annotates periods of sinus bradycardia, it might be important to know the heart rate threshold used by the algorithm.

See the series control variable discussion for additional details and examples.

This is an example of the ECG recording device authoring a set of automatic annotations:

```
<subjectOf>
  <annotationSet>
    <activityTime value="20021122091000.000"/>
    <author>
      <assignedEntity>
        <id root="2.16.840.1.113883.3.5" extension="45"/>
```

```
            <assignedAuthorType>
               <assignedDevice>
                  <id root="1.3.6.1.4.1.57054" extension="SN234-AR9-102993"/>
                  <code code="12LEAD_ELECTROCARDIOGRAPH" codeSystem=""/>
                  <manufacturerModelName>Electrograph
250</manufacturerModelName>
                  <softwareName>Rx 5.3</softwareName>
                  <playedManufacturedDevice>
                     <manufacturerOrganization>
                        <id root="1.3.6.1.4.1.57054"/>
                        <name>ECG Devices By Smith, Inc.</name>
                     </manufacturerOrganization>
                  </playedManufacturedDevice>
               </assignedDevice>
            </assignedAuthorType>
            <representedAuthoringOrganization>
               <name>CRO Electrocardiograph Lenders, Inc.</name>
               <identification>
                  <id root="2.3.6.1.4.1.94368"/>
               </identification>
            </representedAuthoringOrganization>
         </assignedEntity>
      </author>
   </subjectOf>
</annotationSet>
```

This is an example of a ECG core laboratory technician authoring a set of annotations:

```
<subjectOf>
   <annotationSet>
      <activityTime>
         <low value="20021123134500"
         <high value="20021123135800"
      </activityTime>
      <author>
         <assignedEntity>
            <id root="2.16.840.1.113883.3.5" extension="OR_TECH_4"/>
            <assignedAuthorType>
               <assignedPerson>
                  <name>JDR</name>
               </assignedPerson>
            </assignedAuthorType>
            <representedAuthoringOrganization>
               <name>ECG Core Lab, Inc.</name>
               <identification>
                  <id root="2.3.6.1.4.1.85944"/>
               </identification>
            </representedAuthoringOrganization>
         </assignedEntity>
      </author>
   </subjectOf>
</annotationSet>
```

AnnotationSet Component *(optional)*

The annotation set is made up of one or more annotations (the components of the set).

Annotation

An "annotation" is an observation made on the series by the annotation set's author. For example, if the electrocardiograph has algorithms to find the beginning of every QRS, an annotation set authored by the electrocardiograph could be made with component annotations for every QRS it finds. If the algorithm can also suggest a disease diagnoses (i.e. "interpretation"), the annotation set could include interpretation statements. If the algorithm can measure the heart rate, the measured rate can be included as an annotation.

Code

Required: The type of annotation (i.e. the type of observation made). Codes for ECG waveform annotations come from the MDC vocabulary (OID="2.16.840.1.113883.6.24"). A few examples are:

- **MDC_ECG_WAVC** – a component wave
- **MDC_ECG_ECG_TIME_PD_QT** – the time duration of the QT interval

text

Optional: If the annotation can't be described using a simple value, this attribute can accommodate a wide range of things like images, free text, etc. See the HL7 specification for details.

Value

Optional: The observed value. If the observation is the time duration of the QT interval, this would contain the observed value, say "367 ms". If the observation is a wave component, the value is the type of wave component observed. Coded values, like types of wave components, come from the MDC vocabulary (OID="2.16.840.1.113883.6.24"). A few examples are:

- **MDC_ECG_WAVC_QRSWAVE** – QRS wave
- **MDC_ECG_WAVC_TWAVE** – T wave

supportingROI

Specifies where the observation was made within the series.

Code

Required: Specifies if the ROI is fully specified or partially specified by its component boundaries.

A fully specified ROI has all the boundaries defining the parts of all the named sequence codes considered part of the region. Any sequence codes not having boundaries are not part of the region. For example, a series for a 12-lead ECG will have 13 sequence codes, one for time and 12 for the 12 leads. If a QRS wave is observed in lead II, the region would have 2 boundaries: a time boundary indicating the beginning and ending of the QRS wave, and unvalued boundary for lead II. All other unnamed leads would not be part of the region.

A partially specified ROI includes all named sequences by default unless a boundary specifies otherwise. For example, a series for a 12-lead ECG will have 13 sequence codes,

one for time and 12 for the 12 leads. If a "global" QRS onset were observed using all the leads, the region would have 1 boundary: a time boundary indicating the beginning of the QRS wave. Because no boundaries are given for the leads, all the leads are considered part of the region.

Codes for this come from the HL7 V3 ActCode vocabulary, OID=" 2.16.840.1.113883.5.4". Allowed codes are:

- **ROIPS** – Partially specified region of interest. A partially specified bounded Region of Interest (ROI) specifies a ROI in which at least all values in the dimensions specified by the boundary criteria participate. For example, if an episode of ventricular fibrillations (Vfib) is observed, it usually doesn't make sense to exclude any ECG leads from the observation and the partially specified ROI would contain only one boundary for time indicating the time interval where Vfib was observed.

- **ROIFS** – Fully specified region of interest. A fully specified bounded Region of Interest (ROI) delineates a ROI in which only those dimensions participate that are specified by boundary criteria, whereas all other dimensions are excluded. For example a ROI to mark an episode of "ST elevation" in a subset of the ECG leads V2, V3, and V4 would include 4 boundaries, one each for time, V2, V3, and V4.

Boundary

A boundary specifies the part of a series dimension (sequence code) included in the region. For example, the region for a QRS wave will have a boundary code for time and a value indicating the time interval. The code used must be a code that exists in the series. It is not allowed, for example, to use a code for absolute time in the series data, but a code for relative time in a boundary.

If the entire named dimension is part of the region, for example all voltage values in lead II, then no value or range of values is necessary. Values are only necessary if a subset of the dimension is included in the region.

Code

Required: The code naming a dimension of the series. Must be a code from the series.

Value

Optional: The value, range of values, or list of values included from the dimension.

The following example shows the annotation the beginning and end of the "global" P wave using a partially specified ROI:

```
<component>
   <annotation>
      <code code="MDC_ECG_BEAT" codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi:type="CE" code="MDC_ECG_BEAT_NORMAL"
codeSystem="2.16.840.1.113883.6.24"/>
      <component>
         <annotation>
            <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi :type="CE" code="MDC_ECG_WAVC_PWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
            <support>
               <supportingROI>
                  <code code="ROIPS" codeSystem="2.16.840.1.113883.5.4"/>
                  <component>
```

```
                    <boundary>
                        <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                        <value xsi:type="IVL_TS">
                            <low value="20021122091000.122"/>
                            <high value="20021122091000.224"/>
                        </value>
                    </boundary>
                </component>
            </supportingROI>
        </support>
      </annotation>
    </component>
  </component>
</annotation>
```

Appendix A: Discussion of UIDs

HL7 Unique Identifiers (UIDs) identify particular entities and acts. UIDs must be universally unique; that is, they can never be assigned to another entity or act by anything else, ever. However, the inverse is not necessarily true. A particular entity or act can have multiple UIDs assigned to it. For example, an ECG core lab may read ECGs for 2 sponsors. Each sponsor may have its own UID assigned to that core lab. The only thing guaranteed is that those UIDs will never assigned to another core lab (or anything else for that matter).

HL7 UIDs have 2 parts: the *root* and the *extension*. The root is the form of an OID or UUID. The extension is free text. The combination of the root and extension together is an HL7 UID and must be universally unique, forever. The root is always required, but the extension is optional.

OIDs, or Object Identifiers, are a managed hierarchy of integers separated by dots. Each dot represents another level in the hierarchy. Much like DNS names on the Internet, an organization responsible for its part of the hierarchy assigns identifiers under its node. Every organization needing to create OIDs to identify things it manages must first request a unique prefix[1]. In other words, the organization must be given a part of the hierarchy to manage for its own purposes.

For example, the HL7 standard organization has assigned the CPT-4 external coding system the OID "2.16.840.1.113883.6.12". The parts of the OID break down this way:

- 2   ISO/ITU-T jointly assigned OIDs
- 2.16   Joint assignments by country
- 2.16.840   USA
- 2.16.840.1   US company arc
- 2.16.840.1.113883   Health Level Seven, Inc.
- 2.16.840.1.113883.6.12   CPT-4 Vocabulary

Once an organization obtains a unique prefix to use for generating its OIDs, that organization can choose any scheme it wishes for managing its unique identifiers. It can create an arbitrarily deep and complex hierarchy to suite its needs. As a simple example, if a sponsor is assigned the prefix "X" (X is just a placeholder in this example), it could create a hierarchy this way:

- X.1 – study protocols
    - X.1.1 – protocol to study QT prolongation of drug A
    - X.1.2 – protocol to study liver toxicity of drug B
    - X.1.3 – etc.
- X.2 – studies
    - X.2.1 – study using protocol X.1.3
    - X.2.2 – study using protocol X.1.54644
    - X.2.3 – etc.
- X.3 – investigators
    - X.3.1 – Dr. Smith
    - X.3.2 – Dr. Jones

---

[1]ANSI (http://www.ansi.org) can assign OIDs for US organizations. Free organization prefixes can be obtained from IANA (http://www.iana.org) and Dave Harvey (http://www.medicalconnections.co.uk).

- o   X.3.3 – etc.
- X.4 – study sites (if different from investigators)
  - o   X.4.1 – sites for study X.2.435
    - X.4.1.1 – 1st Clinic of Salem
    - X.4.1.2 – River City Cardiac Center
  - o   X.4.2 – sites for study X.2.81
    - X.4.2.1 – River City Cardiac Center
    - X.4.2.2 – Renal Clinic on National Avenue
- X.5 – subjects
  - o   X.5.1 – subjects in study 345
    - X.5.1.1 – subject 123
    - X.5.1.2 – subject 124
    - X.5.1.3 – subject 125
  - o   X.5.2 – subjects in study 22
    - X.5.2.1 – subject 532
    - X.5.2.2 – subject 533
  - o   Etc.

UUIDs, or Universal Unique Identifiers, are unmanaged 128-bit numbers generated by computer algorithms. The algorithms use information including the network hardware address, the date and time, and random seeds to make new identifiers that will never be repeated again by another computer in the future. The 128-bit numbers are expressed as strings using 32 hexadecimal characters and 3 dashes. The string version of UUIDs is used in HL7 standards. "61d1a24f-b47e-41aa-ae95-f8ac302f4eeb" is an example of a UUID looks like as a string.

Creators of aECGs are free to decide which type of UID to use for the root. It is common to use OIDs for things that are managed by organizations, people, and procedures. Things like the study protocol, study, sponsor, investigator, site, subject, etc. are all good candidates for OIDs assigned by the sponsor and/or core laboratory. UIDs for things like the *AnnotatedECG* and *series* which are produced by computer software are good candidates for UUIDs.

It is expected that the extension part of the UID be used for the traditional identifier. The root can be viewed as something necessary to comply with the HL7 standard so the identifier is globally unique, and the extension is where the "user friendly" identifier goes. For example, if a sponsor normally identifies the investigator Dr. Smith as "INV-334", then "INV-334" goes into the extension.

Appendix B: Discussion of Codes and Coding Systems

Note: the terms "coding system" and "vocabulary" are used synonymously.

The aECG standard contains many coded concepts. There are codes that identify particular parts of the protocol, types of ECG waveforms, annotations, device settings, etc. In HL7, a code is a string that has been assigned a specific meaning by a coding system (a.k.a. vocabulary).

Coding systems are either recognized by HL7 or are local. When possible, HL7-recognized coding systems should be used so the code meaning can be known outside the locale. However, it is not always possible to use HL7-recognized coding systems. For example, the code "5MG-ORAL" for a reference event in a particular protocol will not likely be defined in an HL7-recognized coding system.

When using a code in an HL7 standard, it is not enough to just give the code; the coding system giving that code meaning must also be identified. Coding systems are identified using OIDs in HL7 standards. If the coding system is recognized by HL7, the HL7-assigned OID must be used to identify it. Otherwise, if the coding system is locally defined, the organization responsible for the coding system must assign it an OID.

In another appendix, several HL7-recognized coding systems used in the aECG standard are presented. However, there will most likely always be locally defined codes as well. All codes are expected to come from HL7-recognized coding systems except the following aECG concepts defined by the study protocol:

- timepointEvent
- protocolTimepointEvent
- relativeTimepoint

If codes for these concepts are defined by a study protocol, the coding system OID should then be an OID unique to that protocol. If, on the other hand, the codes for these concepts come from a study-independent coding system maintained by the sponsor for all protocols, the coding system OID would not be protocol-specific, but still be specific to the sponsor.

Appendix C: Discussion of Timestamps

The HL7 date/time datatype has a variable resolution starting with naming the 4-digit year:

- 2004

Finer resolution can be added by appending additional information. Next comes the 2-digit month (January is 01, December is 12):

200410   October, 2004

Then the 2-digit day of the month:

20041004   October 4, 2004

Then the 2-digit hour ranging from 00 to 23:

2004100415   October 4, 2004 3:00 pm

Then the 2-digit minute ranging from 00 to 59:

200410041545   October 4, 2004 3:45 pm

Then the 2-digit seconds ranging from 00 to 59:

20041004154508   October 4, 2004 3:45:08 pm

Then, if fractional seconds are known, a decimal point can be used between the seconds and fractions of seconds:

20041004154508.034   October 4, 2004 3:45:08 pm and 34 milliseconds

There are several timestamps in the aECG standard. There are both *effective* times and *actual* times used in aECG. An effective time in HL7 is the focal time related to the act itself. For example, the effective time of an ECG is the time when the ECG was recorded from the subject. In other words, the effective time is when the act occurred. An actual time is more about administrative things, like when a person analyzed the data, possibly hours or days after the data was collected from the subject. For example, the activity time of an annotation set is when the cardiologist analyzed the waveforms and made the measurements.

The times are expressed as an *interval* of time with a low and high boundary. If a time interval is not appropriate and there is only a single point in time, specify the *center*. If the time really is an interval, but only one of the boundaries is known, then just name the known boundary. For example, if it's known that a study started 20031207, but it's know known exactly when it ended, then specify the low boundary and leave out the high boundary.

Following is a table of the different times found in aECG with an explanation for each:

aECG time field	How to use
AnnotatedECG/effectiveTime (Required)	This is the effective time for the annotated ECG. It should match the time assigned to the ECG findings derived from the waveforms within. For example, if the aECG contains 3 series taken over a period of 2 minutes, and a single QT interval is derived from measurements of 3 beats in each of the 3 series, this effective time is the time assigned the derived QT value in the analysis dataset.
	If the aECG contains only a single series, this effective time is most always the same as the effective time of the contained series.

timepointEvent/effectiveTime (Optional)	This is the time range of the timepointEvent during which the ECG waveforms were collected.
Series/effectiveTime (Required)	This is the time of ECG waveform collection. This is almost always the time given by the ECG waveform recording device.
secondaryPerformer/time (Optional)	This is the time range with the technician was involved in collecting the ECG waveforms. For a resting ECG, this time may be the same time as the series/effectiveTime. However, a Holter recording might have a hookup technician who was involved at the beginning of the recording, a disconnect technician who was involved at the end of the recording, and an analysis technician who was involved in the analysis and strip selection process.
annotationSet/activityTime (Optional)	This is the time range the author of the annotationSet spent making the annotations.
clinicalTrial/activityTime (Optional)	This is the range of time the trial took place.

Appendix D: Required Information

The following XML sample is the absolute minimum amount of information that validates with the aECG schema.

```xml
<AnnotatedECG>
   <id root="61d1a24f-b47e-41aa-ae95-f8ac302f4eeb"/>
   <code code="93000" codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"/>
   <effectiveTime>
     <center value="20021122091000"/>
   </effectiveTime>
   <componentOf>
      <timepointEvent>
         <componentOf>
            <subjectAssignment>
               <subject>
                  <trialSubject>
                     <id root="2.16.840.1.113883.3.456" extension="SBJ-
123"/>
                  </trialSubject>
               </subject>
               <componentOf>
                  <clinicalTrial>
                     <id root="2.16.840.1.113883.3.123" extension="PUK-
123-TRL-1"/>
                  </clinicalTrial>
               </componentOf>
            </subjectAssignment>
         </componentOf>
      </timepointEvent>
   </componentOf>
</AnnotatedECG>
```

The XML sample above has the minimal information required: a UID for the aECG, a code for the type of aECG (which is fixed for now), an effective time for the aECG, a UID for the subject, and a UID for the trial. Even though it's not required by the XML schema, it doesn't make much sense to have an aECG without waveforms. The following example shows the same minimal aECG with one waveform (Lead II sampled at 500 Hz):

```xml
<AnnotatedECG>
   <id root="61d1a24f-b47e-41aa-ae95-f8ac302f4eeb"/>
   <code code="93000" codeSystem="2.16.840.1.113883.6.12"
codeSystemName="CPT-4"/>
   <effectiveTime>
     <center value="20021122091000"/>
   </effectiveTime>
   <componentOf>
      <timepointEvent>
         <componentOf>
            <subjectAssignment>
               <subject>
                  <trialSubject>
                     <id root="2.16.840.1.113883.3.456" extension="SBJ-
123"/>
                  </trialSubject>
```

```
                </subject>
                <componentOf>
                    <clinicalTrial>
                        <id root="2.16.840.1.113883.3.123" extension="PUK-
123-TRL-1"/>
                    </clinicalTrial>
                </componentOf>
            </subjectAssignment>
        </componentOf>
      </timepointEvent>
   </componentOf>
   <component>
     <series>
        <code code="RHYTHM" codeSystem="2.16.840.1.113883.5.4"/>
        <effectiveTime>
           <low value="20021122091000"/>
           <high value="20021122091010"/>
        </effectiveTime>
        <component>
           <sequenceSet>
              <component>
                 <sequence>
                    <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                    <value xsi:type="GLIST_TS">
                       <head value="20021122091000"/>
                       <increment value="0.002" unit="s"/>
                    </value>
                 </sequence>
              </component>
              <component>
                 <sequence classCode="OBS">
                    <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                    <value xsi:type="SLIST_PQ">
                       <origin value="0" unit="uV"/>
                       <scale value="2.5" unit="uV"/>
                       <digits>-2 -2 -2 -2 -3 -4 -3 -5 -5 -4 -6 -9 -9 ...
                       </digits>
                    </value>
                 </sequence>
              </component>
           </sequenceSet>
        </component>
     </series>
   </component>
</AnnotatedECG>
```

Other information can be required if optional information at a higher level is included. For example, the protocol is an optional part of aECG. However, if it's included, the UID of the protocol is then required. Please consult the HL7 standard and XML schema for this type of information.

Appendix E: Discussion of ECG Context

It's not strictly required by the aECG standard, but it's strongly recommended to include information about the context of the aECG within the trial and protocol. There are 4 key aECG concepts for capturing the context of the aECG: treatmentGroup, timepointEvent, referenceEvent, and relativeTimepoint.

The treatmentGroup is a grouping of subjects having a common treatment protocol. For example, one treatment group in a trial will get 5 mg, then placebo, then 10 mg. All the subjects in that treatment group receive those dosages in the same order. Another treatment group may receive the dosages in a different order: placebo, 10 mg, then 5 mg. For those familiar with the CDISC SDTM standard, the treatment group is closest to the SDTM *Arm* concept.

The treatmentGroup is identified by using a code. The code most likely comes from the trial protocol, and the coding system OID would most likely identify that protocol. For example, if the protocol refers to a particular treatment group as "5-P-10", and the OID assigned to the protocol is "2.16.840.1.113883.3.1", then the treatment group would be identified like so:

```
<treatmentGroupAssignment>
    <code code="5-P-10" codeSystem="2.16.840.1.113883.3.1"/>
</treatmentGroupAssignment>
```

ECG assessments are made at relative time points. These assessments are relative to a reference event. The reference event is usually an intervention like a drug dosage. The protocol will group reference events and relative time points into protocol time point events. For those familiar with the CDISC SDTM standard, the protocol time point event is most similar to an *Element* or *Visit* (depending on the protocol).

Codes for the reference events, relative time points, and protocol time point events are normally defined by the trial protocol. For example, if the reference event is "5MG-ORAL", the relative time point is "2HR", the protocol time point event is "VISIT_2", and the OID assigned to the protocol is "2.16.840.1.113883.3.1", then they would be coded in an aECG like so:

```
<definition>
    <relativeTimepoint>
        <code code="2HR" codeSystem="2.16.840.1.113883.3.1"/>
        <componentOf>
            <protocolTimepointEvent>
                <code code="VISIT_2" codeSystem="2.16.840.1.113883.3.1"/>
                <component>
                    <referenceEvent>
                        <code code="5MG-ORAL" codeSystem="2.16.840.1.113883.3.1"/>
                    </referenceEvent>
                </component>
            </protocolTimepointEvent>
        </componentOf>
    </relativeTimepoint>
</definition>
```

Finally, the time point event of an aECG names the actual time point event the aECG was taken within. This is most often the same as the protocol time point event if things were to plan. However, if the time point event is not per protocol, then this names the actual time point event.

Appendix F: Linking CDISC SDTM to HL7 aECG

aECGs will be provided to regulatory agencies in support of ECG findings. Those ECG findings will be provided according to the CDISC SDTM standard. The SDTM EG tabulation contains the ECG findings.

Each finding (or row) in the EG tabulation should be linked to an aECG containing the annotated waveforms supporting the finding. The way to link the EG row to an aECG is by putting the aECG's UID into the EGREFID field. That is, the contents of the **root** attribute of the **id** element contained by the **AnnotatedECG** element should be copied into the **EGREFID** field.

In addition to linking the EG rows to aECGs, concepts that overlap between SDTM and aECG should be understood. The overlapping concepts to be understood are the aECG TimepointEvent, RelativeTimepoint, and ReferenceEvent.

The aECG **TimepointEvent** act maps best to the SDTM **visit** concept. The aECG TimepointEvent code identifies which visit and must be unique within the study. The SDTM VISITNUM or VISITDY are most likely the best fields to map to the aECG TimepointEvent code. However VISITNUM is strictly an integer for sorting purposes and the TimepointEvent code can be a mnemonic. Examples of VISITNUM are "1", "2", "3", etc., but the TimepointEvent code could be "VISIT 1", "VISIT 2", "V 1", "V2", "DAY 1", "DAY 2", or just "1", "2", "3", etc. It is left up to the discretion of the sponsor to decide the exact coding of the aECG TimepointEvent codes.

The aECG **RelativeTimepoint** act maps best to the SDTM **planned time point** concept. The aECG RelativeTimepoint code identifies the planned time point relative to a reference event (like a dosage). Often these planned time points are named by the number of hours past the dosage, like "0" for baseline, "0.5" for ½ hour after dosage, etc. SDTM has the fields EGTPT for a short text description of the planned time point, EGTPTNUM for sorting the planned time points, and EGELTM for the elapsed time between the planned time point and reference event. Any of these SDTM fields could be mapped to the aECG RelativeTimepoint code, but it is left up to the sponsor to decide the exact coding of the aECG RelativeTimepoint codes.

Likewise, the aECG **ReferenceEvent** act maps best to the SDTM **time point reference** concept. The aECG ReferenceEvent code identifies the reference event the relative time points are relative to. The closest STDM field is EGTPTREF, but this is just a short text description. There is not a EGTPTREFNUM field for ordering the reference time points. Again, it is ultimately up to the sponsor to decide how to code the ReferenceEvent in aECG.

Appendix G: Examples of Common ECG Annotations

QRS-Wave Annotation

```
<annotation>
   <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
   <value xsi :type="CE" code="MDC_ECG_WAVC_QRSWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
   <support>
      <supportingROI>
         <code code="ROIPS" codeSystem="2.16.840.1.113883.5.4"/>
         <component>
            <boundary>
               <code code="TIME_RELATIVE" codeSystem="2.16.840.1.113883.5.4"/>
               <value xsi:type="IVL_PQ">
                  <low value="434" unit="ms"/>
                  <high value="554" unit="ms"/>
               </value>
            </boundary>
         </component>
      </supportingROI>
   </support>
</annotation>
```

The code "MDC_ECG_WAVC" says this annotation is an ECG waveform component. The value "MDC_ECG_WAVC_QRSWAVE" says the type of waveform component is the QRS. The ROI code "ROIPS" says this ROI is partially specified, i.e. it applies to all leads. The boundary code "TIME_RELATIVE" means the boundary is specified in relative time – relative to the beginning of the series. The value of the boundary is a physical quantity interval starting at 434 and ending 554, in units of milliseconds.

T-Offset Annotation

```
<annotation>
   <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
   <value xsi:type="CE" code="MDC_ECG_WAVC_TWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
   <support>
      <supportingROI>
         <code code="ROIPS" codeSystem="2.16.840.1.113883.5.4"/>
         <component>
            <boundary>
               <code code="TIME_RELATIVE" codeSystem="2.16.840.1.113883.5.4"/>
               <value xsi:type="IVL_PQ">
                  <high value="854" unit="ms"/>
               </value>
            </boundary>
         </component>
      </supportingROI>
   </support>
</annotation>
```

Note that the boundary is still a physical quantity interval. However, only the high part of the interval is specified. This annotation is saying that the T-wave has a beginning and ending, but only the ending is given as 854 ms from the beginning of the series.

P-Wave Annotation

```
<annotation>
   <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
   <value xsi:type="CE" code="MDC_ECG_WAVC_PWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
   <support>
      <supportingROI>
         <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
         <component>
            <boundary>
               <code code="TIME_RELATIVE" codeSystem="2.16.840.1.113883.5.4"/>
               <value xsi:type="IVL_PQ">
                  <low value="286" unit="ms"/>
                  <high value="388" unit="ms"/>
               </value>
            </boundary>
         </component>
         <component>
            <boundary>
               <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
            </boundary>
         </component>
      </supportingROI>
   </support>
</annotation>
```

This example is similar to the QRS-Wave example except the code for the waveform component indicates the P-wave instead of QRS. Also, this uses a fully specified ROI (code "ROIFS") which means all the boundaries are specified. This ROI is on lead II only. Note the lead II boundary does not have any values because *all* voltage values of lead II are included in the ROI.

R-Peak Time Annotation

```
<annotation>
   <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
   <value xsi :type="CE" code="MDC_ECG_WAVC_RWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
   <component>
      <annotation>
         <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
         <value xsi :type="CE" code="MDC_ECG_WAVC_PEAK"
codeSystem="2.16.840.1.113883.6.24"/>
         <support>
            <supportingROI>
               <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
               <component>
                  <boundary>
                     <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                     <value xsi:type="TS" value="20030218210053.572"/>
                  </boundary>
               </component>
```

```
            <component>
                <boundary>
                    <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                </boundary>
            </component>
        </supportingROI>
    </support>
  </annotation>
  </component>
</annotation>
```

This example shows how annotations are nested to create more complex annotations. The top-level annotation is for the R-wave, and nested inside is a *peak* annotation. There is no supporting ROI for the R-wave, so we don't know where the R-wave begins and ends. There is only an annotation for the peak. Note that the time boundary is expressed as a single point in time and not as an interval (which makes sense for a peak annotation). Also note that the time in this example is expressed as an absolute time stamp. The ROI time boundary must match the series time sequence (either ABSOLUTE or RELATIVE time).

R-Peak Amplitude Annotation

```
<annotation>
  <code code="MDC_ECG_AMPL_R" codeSystem="2.16.840.1.113883.6.24"/>
codeSystem="2.16.840.1.113883.6.24"/>
  <component>
    <annotation>
      <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi :type="CE" code="MDC_ECG_WAVC_ISO"
codeSystem="2.16.840.1.113883.6.24"/>
      <support>
        <supportingROI>
          <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
          <component>
            <boundary>
              <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
              <value xsi:type="IVL_TS">
                <low value="20030325083133.062"/>
                <high value="20030325083134.062"/>
              </value>
            </boundary>
          </component>
          <component>
            <boundary>
              <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
              <value xsi:type="PQ" value="50" unit="uV"/>
            </boundary>
          </component>
        </supportingROI>
      </support>
    </annotation>
  </component>
  <component>
    <annotation>
```

```
        <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
        <value xsi:type="CE" code="MDC_ECG_WAVC_RWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
      <component>
        <annotation>
          <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
          <value xsi:type="CE" code="MDC_ECG_WAVC_PEAK"
codeSystem="2.16.840.1.113883.6.24"/>
          <support>
            <supportingROI>
              <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
              <component>
                <boundary>
                  <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                    <value xsi:type="IVL_TS">
                      <low value="20030325083133.062"/>
                      <high value="20030325083134.062"/>
                    </value>
                </boundary>
              </component>
              <component>
                <boundary>
                  <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                    <value xsi:type="PQ" value="785" unit="uV"/>
                </boundary>
              </component>
            </supportingROI>
          </support>
        </annotation>
      </component>
    </annotation>
  </component>
</annotation>
```

The R-amplitude annotation is composed of 2 child annotations, one for the iso-electric level of the beat, and a second for the R-peak level of the beat. Notice the iso-electric level's fully specified boundary has a beginning and end value in time to denote the approximate beginning and ending of the beat. The iso-electric level is specified as the value in the Lead II boundary. The R-peak annotation is similar to the R-peak time example except the region is defines the voltage level of the R-peak as a value of the Lead II boundary. The time boundary has a beginning and ending for the approximate beginning and ending of the beat.

QT Interval Annotation

```
<annotation>
  <code code="MDC_ECG_TIME_PD_QT" codeSystem="2.16.840.1.113883.6.24"/>
  <value xsi:type="PQ" value="343" unit="ms"/>
  <component>
    <annotation>
      <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi:type="CE" code="MDC_ECG_WAVC_QRSWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
      <support>
        <supportingROI>
```

```
            <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
            <component>
              <boundary>
                <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                <value xsi:type="IVL_TS">
                  <low value="20030325083133.453"/>
                </value>
              </boundary>
            </component>
            <component>
              <boundary>
                <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
              </boundary>
            </component>
          </supportingROI>
        </support>
      </annotation>
  </component>
  <component>
    <annotation>
        <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
        <value xsi:type="CE" code="MDC_ECG_WAVC_TWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
        <support>
          <supportingROI>
            <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
            <component>
              <boundary>
                <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                <value xsi:type="IVL_TS">
                  <high value="20030325083134.796"/>
                </value>
              </boundary>
            </component>
            <component>
              <boundary>
                <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
              </boundary>
            </component>
          </supportingROI>
        </support>
      </annotation>
  </component>
</annotation>
```

This QT annotation in lead II is composed of 2 child annotations, one for the QRS onset and another for the T offset. Each child annotation is fully specified using time interval boundaries and a boundary indicating lead II. The QRS boundary just specifies the beginning of the QRS, and the T boundary just specifies the end of the T. Notice that the actual *value* of the QT interval is given as the value of the top-level QT annotation.

QTc Interval Annotation

```xml
<annotation>
  <code code="MDC_ECG_TIME_PD_QTc" codeSystem="2.16.840.1.113883.6.24"/>
  <component>
    <annotation>
      <code code="MDC_ECG_TIME_PD_QTcB"
codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi:type="PQ" value="432" unit="ms"/>
    </annotation>
  </component>
  <component>
    <annotation>
      <code code="MDC_ECG_TIME_PD_QTcF"
codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi:type="PQ" value="446" unit="ms"/>
    </annotation>
  </component>
  <component>
    <annotation>
      <code code="MDC_ECG_TIME_PD_QT" codeSystem="2.16.840.1.113883.6.24"/>
codeSystem="2.16.840.1.113883.6.24"/>
      <component>
        <annotation>
          <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
          <value xsi:type="CE" code="MDC_ECG_WAVC_QRSWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
          <support>
            <supportingROI>
              <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
              <component>
                <boundary>
                  <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                  <value xsi:type="IVL_TS">
                    <low value="20030325083133.453"/>
                  </value>
                </boundary>
              </component>
              <component>
                <boundary>
                  <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                </boundary>
              </component>
            </supportingROI>
          </support>
        </annotation>
      </component>
      <component>
        <annotation>
          <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
          <value xsi:type="CE" code="MDC_ECG_WAVC_TWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
          <support>
            <supportingROI>
              <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
```

```
                <component>
                   <boundary>
                      <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                         <value xsi:type="IVL_TS">
                            <high value="20030325083134.796"/>
                         </value>
                   </boundary>
                </component>
                <component>
                   <boundary>
                      <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                   </boundary>
                </component>
             </supportingROI>
          </support>
       </annotation>
    </component>
  </annotation>
</component>
<component>
   <annotation>
      <code code="MDC_ECG_TIME_PD_RR" codeSystem="2.16.840.1.113883.6.24"/>
      <component>
         <annotation>
            <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi:type="CE" code="MDC_ECG_WAVC_RWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
            <component>
               <annotation>
                  <code code="MDC_ECG_WAVC"
codeSystem="2.16.840.1.113883.6.24"/>
                  <value xsi:type="CE" code="MDC_ECG_WAVC_PEAK"
codeSystem="2.16.840.1.113883.6.24"/>
                  <support>
                     <supportingROI>
                        <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
                        <component>
                           <boundary>
                              <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                                 <value xsi:type="TS" value="20030325083133.492"/>
                           </boundary>
                        </component>
                        <component>
                           <boundary>
                              <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                           </boundary>
                        </component>
                     </supportingROI>
                  </support>
               </annotation>
            </component>
         </annotation>
      </component>
```

```
        <component>
          <annotation>
            <code code="MDC_ECG_WAVC" codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi:type="CE" code="MDC_ECG_WAVC_RWAVE"
codeSystem="2.16.840.1.113883.6.24"/>
            <component>
              <annotation>
                <code code="MDC_ECG_WAVC"
codeSystem="2.16.840.1.113883.6.24"/>
                <value xsi:type="CE" code="MDC_ECG_WAVC_PEAK"
codeSystem="2.16.840.1.113883.6.24"/>
                <support>
                  <supportingROI>
                    <code code="ROIFS" codeSystem="2.16.840.1.113883.5.4"/>
                    <component>
                      <boundary>
                        <code code="TIME_ABSOLUTE"
codeSystem="2.16.840.1.113883.5.4"/>
                          <value xsi:type="TS" value="20030325083132.534"/>
                      </boundary>
                    </component>
                    <component>
                      <boundary>
                        <code code="MDC_ECG_LEAD_II"
codeSystem="2.16.840.1.113883.6.24"/>
                      </boundary>
                    </component>
                  </supportingROI>
                </support>
              </annotation>
            </component>
          </annotation>
        </component>
      </annotation>
   </component>
</annotation>
```

This QTc annotation in lead II is composed of 2 child annotations, one for the QT interval, and the other for an RR interval. The QT interval is composed of a nested QRS onset annotation and a T offset annotation from a previous QT example. The RR interval annotation is composed of 2 nested R-peak time annotations similar to a previous R-peak time annotation example. This example also shows how to include the derived QTcB and QTcF values using the Bazett and Fridericia methods.

Interpretation Statement Annotations

```
<annotation>
  <code code="MDC_ECG_INTERPRETATION" codeSystem="2.16.840.1.113883.6.24"/>
  <component>
    <annotation>
      <code code="MDC_ECG_INTERPRETATION_STATEMENT"
codeSystem="2.16.840.1.113883.6.24"/>
      <value xsi:type="ST">
         SINUS RHYTHM
      </value>
```

```
            </annotation>
    </component>
    <component>
        <annotation>
            <code code="MDC_ECG_INTERPRETATION_STATEMENT"
codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi:type="ST">
                LEFT ANTERIOR FASCICULAR BLOCK
            </value>
        </annotation>
    </component>
    <component>
        <annotation>
            <code code="MDC_ECG_INTERPRETATION_STATEMENT"
codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi:type="ST">
                ANTEROLATERAL INFARCT, PROBABLY RECENT
            </value>
        </annotation>
    </component>
    <component>
        <annotation>
            <code code="MDC_ECG_INTERPRETATION_SUMMARY"
codeSystem="2.16.840.1.113883.6.24"/>
            <value xsi:type="ST">
                ABNORMAL ECG
            </value>
        </annotation>
    </component>
</annotation>
```

This example shows how to encode a series of interpretation statements. These statements can be automatically generated by ECG analysis software in ECG devices or management systems, or can be authored by a cardiologist. Note that the whole set of statements are grouped under one parent MDC_ECG_INTERPREATION annotation. This allows the set of statements to be treated as a single unit, and it allows for a single MDC_ECG_INTERPRETATION_SUMMARY for summarizing everything into a single statement.

Appendix H: FDA Considerations

Because the aECG standard was created in response to the needs of the FDA, a good understanding of what the FDA was looking for and intending to do with the aECG data was developed. This appendix addresses some things to consider when making aECG data available to the FDA for a drug application. This appendix is written to the best of the author's knowledge. It should not be considered an official FDA policy.

Annotations

The annotations contained in an aECG made available to the FDA should contain all annotations supporting all the ECG findings made from the waveforms. For example, if 3 QT intervals were measured, there should be 3 sets of QRS onset and T offset annotations on the beats that were measured.

The aECG standard does not support audit trails. In some core laboratory workflows, a computer algorithm in the ECG device will make automatic QT measurements on all the beats or a representative beat. An aECG file produced by that device will have an annotation set with all the beats or representative beat annotated. Downstream a core laboratory cardiologist may choose 3 beats and make his own measurements on them. A new aECG file is produced after the manual measurements are made. This aECG file *could* have 2 annotations sets, the first set produced by the device, and a second set produced by the cardiologist. If this aECG file were provided to the FDA, the FDA would have no way of knowing which QT annotations were actually used in the study analysis. If there was too much noise in a few of the beats and the computer algorithm was a little off for those QTs, the FDA may question those annotations. The FDA would have no way of knowing those QTs where not part of the study analysis. Sponsors should carefully consider which annotations to make available to the FDA in support of their ECG findings.

ECG Context

The FDA is likely to use a data management system to facilitate the review of the aECG data. Reviewers will want to navigate the waveforms in a logical way. Therefore, there will need to be enough information in the aECG files to facilitate the navigation. It is important to include a complete set of context information with the aECGs. This includes the treatment group, time point event, protocol time point event, reference event, and the relative time point. It will be natural for the reviewer to want to see subjects grouped by treatment group, time point events lined up chronologically for a given subject, and reference events and relative time points within the time point event.

Valid aECGs

As far as this author knows, the FDA is only accepting aECGs conforming to the version of the aECG standard approved by the HL7 membership in January 2004. As a minimum, all the aECGs must validate using the aECG schema. Besides that, however, the FDA may also look for other basic information and consistency. For example, known coding systems could be verified and codes used from those systems checked to make sure they are correct. If the FDA can't interpret a code, it may be a problem.

Higher-level consistency could also be checked. For example, if a series of ECG waveforms are encoded using absolute time, but an annotation on that series uses relative time, that annotation is not correct and the FDA would not be able to interpret it. Another example would be an annotation that's made out of the bounds of the waveforms. Annotating a T-offset at 13 seconds on a 10 second waveforms doesn't make sense.

ID Uniqueness and Consistency

Because of the possibility to use a single data management system for reviewing all aECGs at the FDA, it is very important that the aECG UID be unique within the pool of all other aECGs ever produced in the past or in the future by all sponsors. However, it's also important that there not be multiple UIDs for the same aECG. If an aECG needs to be replaced with a corrected one, the UID will be used to identify the aECG being replaced.

The same common sense goes for all other UIDs like subject, trial, protocol, etc. UIDs for different things, like different subjects, must be universally unique from all other subjects in the past and in the future for all sponsors. At the same time, the same UID must be used to refer to the same subject within the trial.

The FDA expects to find the traditional identifiers in the extension part of the UIDs. The traditional identifiers are the same ones used in the SDTM tabulations. There should be consistency between the identifiers in the tabulations and the UID extensions in the aECGs.

Filenames and File Organization

The aECG files will provided to the FDA on a per-study basis. This means that at the very least, the filenames must be unique within the study. This author is not aware of any other restrictions or guidance on the filenames.

At the time of this publishing, the following links provide some relevant information for making aECGs available to the FDA:

- "Electronic Regulatory Submissions and Review"
  http://www.fda.gov/cder/regulatory/ersr/default.htm

- "Providing Regulatory Submissions in Electronic Format — General Considerations"
  http://www.fda.gov/cder/guidance/2867fnl.pdf

- "Study Data Specifications" http://www.fda.gov/cder/regulatory/ersr/5640studydata-v1.pdf

Linkage with CDISC SDTM

The SDTM standard made by CDISC contains a tabulation named "EG" for ECG findings. Those ECG findings are expected to be supported by the annotated ECG waveforms in the aECG files. There are 2 fields in the EG tabulation for establishing the link from the EG row to the aECG that supports it. The EGREFID field should contain the aECG UID. This is the primary way to make the linkage. There is also the EGFXM field for specifying the filename of the aECG. Although this method of linkage is OK when the data is still packaged together in a study, it could be a problem in the more global sense because the filenames are not guaranteed to be unique.

ECG Finding Values

During the development of the aECG standard, the FDA repeatedly expressed their wishes that the actual derived ECG findings not be placed into the aECG itself. These derived findings (e.g. QTcB, PR, RR, etc.) are given to the FDA in tabulations in the CDISC SDTM format. If the findings are also included in the aECG files, there is a potential risk that the values are different in the aECGs and tabulations. If they are different, there will be questions raised about how to interpret the inconsistencies.

Appendix I: Vocabulary Reference

Subject gender

Vocabulary Name:	**AdministrativeGender**
Code System Name:	**AdministrativeGender**
Code System OID:	**2.16.840.1.113883.5.1**

The gender of a person used for administrative purposes.

Code	Display Name	Expansions
F	Female	Female
M	Male	Male
UN	Undifferentiated	The gender of a person could not be uniquely defined as male or female, such as hermaphrodite.

Example of use:

<administrativeGenderCode code=”**M**” codeSystem=”**2.16.840.1.113883.5.1**”
codeSystemName=”**AdministrativeGender**” displayName=”**Male**”/>

Subject race

Vocabulary Name:	**Race**
Code System Name:	**Race**
Code System OID:	**2.16.840.1.113883.5.104**

In the United States, federal standards for classifying data on race determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies and private sector organizations. The federal standards do not conceptually define race, and they recognize the absence of an anthropological or scientific basis for racial classification. Instead, the federal standards acknowledge that race is a social-political construct in which an individual's own identification with one more race categories is preferred to observer identification. The standards use a variety of features to define five minimum race categories. Among these features are descent from "the original peoples" of a specified region or nation. The minimum race categories are American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. The federal standards stipulate that race data need not be limited to the five minimum categories, but any expansion must be collapsible to those categories.

The following list is not fully exhaustive: we added only the first level expansion. For further expansions see HL7 race code vocabulary.

Code	Display Name	Expansions
2028-9	Asian	

Expansion of *ASIAN race*.

Code	Display Name
2029-7	Asian Indian
2030-5	Bangladeshi
2031-3	Bhutanese
2032-1	Burmese
2033-9	Cambodian
2034-7	Chinese
2035-4	Taiwanese
2036-2	Filipino
2037-0	Hmong
2038-8	Indonesian
2039-6	Japanese
2040-4	Korean
2041-2	Laotian
2042-0	Malaysian
2043-8	Okinawan
2044-6	Pakistani
2045-3	Sri Lankan
2046-1	Thai

		2047-9	Vietnamese
		2048-7	Iwo Jiman
		2049-5	Maldivian
		2050-3	Nepalese
		2051-1	Singaporean
		2052-9	Madagascar

2054-5	Black or African American		
		Expansion of *BALCK OR AFRICAN AMERICAN* race.	
		Code	**Display Name**
		2060-2	African
		2056-0	Black
		2058-6	African American
		2067-7	Bahamian
		2068-5	Barbadian
		2069-3	Dominican
		2070-1	Dominica Islander
		2071-9	Haitian
		2072-7	Jamaican
		2073-5	Tobagoan
		2074-3	Trinidadian
		2075-0	West Indian

2076-8	Native Hawaiian or Other Pacific Islander		
		Expansion of *NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER* race.	
		Code	**Display Name**
		2100-6	Melanesian
		2085-9	Micronesian
		2078-4	Polynesian
		2500-7	Other Pacific Islander

1002-5	American Indian or Alaska Native	**Expansion of _AMERICAN INDIAN OR ALASKA NATIVE_ race.**

Code	Display Name
1735-0	Alaska Native
1004-1	American Indian

2106-3	**White**	**Expansion of _WHITE_ race.**

Code	Display Name
2129-5	Arab
2108-9	European
2118-8	Middle Eastern or North African

2131-1	Other Race	

Examples of use:

<raceCode code="**2106-3**" codeSystem="**2.16.840.1.113883.5.104**" codeSystemName="**Race**" displayName="**White**" />

<raceCode code="**2039-6**" codeSystem="**2.16.840.1.113883.5.104**" codeSystemName="**Race**" displayName="**Japanese**" />

Region of interest

Vocabulary Name:	**ActBoundedROICode**
Code System Name:	**ActCode**
Code System OID:	**2.16.840.1.113883.5.4**

Code	Display Name	Definition/Description
ROIFS	fully specified ROI	A fully specified bounded Region of Interest (ROI) delineates a ROI in which only those dimensions participate that are specified by boundary criteria, whereas all other dimensions are excluded. For example a ROI to mark an episode of "ST elevation" in a subset of the EKG leads V2, V3, and V4 would include 4 boundaries, one each for time, V2, V3, and V4.
ROIPS	partially specified ROI	A partially specified bounded Region of Interest (ROI) specifies a ROI in which at least all values in the dimensions specified by the boundary criteria participate. For example, if an episode of ventricular fibrillations (Vfib) is observed, it usually doesn't make sense to exclude any EKG leads from the observation and the partially specified ROI would contain only one boundary for time indicating the time interval where Vfib was observed.

Example of use:

<code code="**ROIFS**" codeSystem="**2.16.840.1.113883.5.4**" codeSystemName="**ActCode**" displayName="**fully specified ROI**" />

Observation series type

<table>
<tr><td colspan="3">Vocabulary Name: **ECGObservationSeriesType**

Code System Name: **ActCode**

Code System OID: **2.16.840.1.113883.5.4**</td></tr>
<tr><td>**Code**</td><td>**Display Name**</td><td>**Definition/Description**</td></tr>
<tr><td>REPRESENTATIVE_BEAT</td><td>ECG representative beat waveforms</td><td>This Observation Series type contains waveforms of a "representative beat" (a.k.a. "median beat" or "average beat"). The waveform samples are measured in relative time, relative to the beginning of the beat as defined by the Observation Series effective time. The waveforms are not directly acquired from the subject, but rather algorithmically derived from the "rhythm" waveforms.</td></tr>
<tr><td>RHYTHM</td><td>ECG rhythm waveforms</td><td>This Observation type contains ECG "rhythm" waveforms. The waveform samples are measured in absolute time (a.k.a. "subject time" or "effective time"). These waveforms are usually "raw" with some minimal amount of noise reduction and baseline filtering applied.</td></tr>
<tr><td colspan="3">Example of use:

<code code="**RHYTHM**" codeSystem="**2.16.840.1.113883.5.4**" codeSystemName="**ActCode**" displayName="**ECG rhythm waveforms**" /></td></tr>
</table>

Observation sequence type

Vocabulary Name: **ECGObservationSequenceType**

Code System Name: **ActCode**

Code System OID: **2.16.840.1.113883.5.4**

This vocabulary includes also the **ECGLeadTypeMDC** vocabulary.

Code	Display Name	Definition/Description
TIME_ABSOLUTE	absolute time sequence	A sequence of values in the "absolute" time domain. This is the same time domain that all HL7 timestamps use. It is time as measured by the Gregorian calendar.
TIME_RELATIVE	relative time sequence	A sequence of values in a "relative" time domain. The time is measured relative to the earliest effective time in the Observation Series containing this sequence.

Example of use:

<code code="**TIME_ABSOLUTE**" codeSystem="**2.16.840.1.113883.5.4**"
codeSystemName="**ActCode**" displayName="**Absolute Time Sequence**" />

ECG Leads

<table>
<tr><td colspan="3">
Vocabulary Name: **ECGLeadTypeMDC**

Code System Name: **MDC**[2]

Code System OID: **2.16.840.1.113883.6.24**
</td></tr>
</table>

Code	Display Name	Definition/Description
MDC_ECG_LEAD_CONFIG	Unspecified lead	Unspecified lead
MDC_ECG_LEAD_I	Lead I	Lead I
MDC_ECG_LEAD_II	Lead II	Lead II
MDC_ECG_LEAD_V1	Lead V1	V1
MDC_ECG_LEAD_V2	Lead V2	V2
MDC_ECG_LEAD_V3	Lead V3	V3
MDC_ECG_LEAD_V4	Lead V4	V4
MDC_ECG_LEAD_V5	Lead V5	V5
MDC_ECG_LEAD_V6	Lead V6	V6
MDC_ECG_LEAD_V7	Lead V7	V7
MDC_ECG_LEAD_V2R	Lead V2R	V2R
MDC_ECG_LEAD_V3R	Lead V3R	V3R
MDC_ECG_LEAD_V4R	Lead V4R	V4R
MDC_ECG_LEAD_V5R	Lead V5R	V5R
MDC_ECG_LEAD_V6R	Lead V6R	V6R
MDC_ECG_LEAD_V7R	Lead V7R	V7R
MDC_ECG_LEAD_X	Lead X	X
MDC_ECG_LEAD_Y	Lead Y	Y
MDC_ECG_LEAD_Z	Lead Z	Z
MDC_ECG_LEAD_CC5	Lead CC5	CC5, per V5 and V5R placement
MDC_ECG_LEAD_CM5	Lead CM5	CM5, per V5 placement
MDC_ECG_LEAD_LA	Lead LA	Left Arm
MDC_ECG_LEAD_RA	Lead RA	Right Arm
MDC_ECG_LEAD_LL	Lead LL	Left Leg
MDC_ECG_LEAD_fI	Lead I	I

---

[2] A special thanks goes to the following IEEE 1073 MDC volunteers for assembling a robust set of codes for ECG leads, annotations, control variables, etc.: Paul Schluter (GE Healthcare Technologies), Barry D. Brown (Mortara Instrument, Inc.), Steve Kordic (GE Healthcare Technologies), and Jan Wittenber (Philips Medical Systems).

MDC_ECG_LEAD_fE	Lead E	E
MDC_ECG_LEAD_fC	Lead C	C
MDC_ECG_LEAD_fA	Lead A	A
MDC_ECG_LEAD_fM	Lead M	M
MDC_ECG_LEAD_fF	Lead F	F
MDC_ECG_LEAD_fH	Lead H	H
MDC_ECG_LEAD_III	Lead III	III
MDC_ECG_LEAD_AVR	Lead aVR	aVR, augmented voltage, right
MDC_ECG_LEAD_AVL	Lead aVL	aVL, augmented voltage, left
MDC_ECG_LEAD_AVF	Lead aVF	aVF, augmented voltage, foot
MDC_ECG_LEAD_AVRneg	Lead –aVR	−aVR
MDC_ECG_LEAD_V8	Lead V8	V8
MDC_ECG_LEAD_V9	Lead V9	V9
MDC_ECG_LEAD_V8R	Lead V8R	V8R
MDC_ECG_LEAD_V9R	Lead V9R	V9R
MDC_ECG_LEAD_D	Lead D	D (Nehb – Dorsal)
MDC_ECG_LEAD_A	Lead A	A (Nehb – Anterior)
MDC_ECG_LEAD_J	Lead J	J (Nehb – Inferior)
MDC_ECG_LEAD_DEFIB	Lead Defib	Defibrillator lead: anterior-lateral
MDC_ECG_LEAD_EXTERN	Lead Extern	External pacing lead: anterior-posterior
MDC_ECG_LEAD_A1	Lead A1	A1 (Auxiliary unipolar lead #1)
MDC_ECG_LEAD_A2	Lead A2	A2 (Auxiliary unipolar lead #2)
MDC_ECG_LEAD_A3	Lead A3	A3 (Auxiliary unipolar lead #3)
MDC_ECG_LEAD_A4	Lead A4	A4 (Auxiliary unipolar lead #4)
MDC_ECG_LEAD_C	Lead Chest	Chest lead
MDC_ECG_LEAD_V	Lead V	Precordial lead
MDC_ECG_LEAD_VR	Lead VR	VR, nonaugmented voltage, vector of RA
MDC_ECG_LEAD_VL	Lead VL	VL, nonaugmented voltage, vector of LA
MDC_ECG_LEAD_VF	Lead VF	VF, nonaugmented voltage, vector of LL
MDC_ECG_LEAD_MCL	Lead MCL	Modified chest lead (left arm indifferent)
MDC_ECG_LEAD_MCL1	Lead MCL1	MCL, per V1 placement
MDC_ECG_LEAD_MCL2	Lead MCL2	MCL, per V2 placement
MDC_ECG_LEAD_MCL3	Lead MCL3	MCL, per V3 placement
MDC_ECG_LEAD_MCL4	Lead MCL4	MCL, per V4 placement
MDC_ECG_LEAD_MCL5	Lead MCL5	MCL, per V5 placement

MDC_ECG_LEAD_MCL6	Lead MCL6	MCL, per V6 placement
MDC_ECG_LEAD_CC	Lead CC	Chest lead (symmetric placement)
MDC_ECG_LEAD_CC1	Lead CC1	CC1, per V1 and V1R placement
MDC_ECG_LEAD_CC2	Lead CC2	CC2, per V2 and V2R placement
MDC_ECG_LEAD_CC3	Lead CC3	CC3, per V3 and V3R placement
MDC_ECG_LEAD_CC4	Lead CC4	CC4, per V4 and V4R placement
MDC_ECG_LEAD_CC6	Lead CC6	CC6, per V6 and V6R placement
MDC_ECG_LEAD_CC7	Lead CC7	CC7, per V7 and V8R placement
MDC_ECG_LEAD_CM	Lead CM	Chest-manubrium
MDC_ECG_LEAD_CM1	Lead CM1	CM1, per V1 placement
MDC_ECG_LEAD_CM2	Lead CM2	CM2, per V2 placement
MDC_ECG_LEAD_CM3	Lead CM3	CM3, per V3 placement
MDC_ECG_LEAD_CM4	Lead CM4	CM4, per V4 placement
MDC_ECG_LEAD_CM6	Lead CM6	CM6, per V6 placement
MDC_ECG_LEAD_CM7	Lead CM7	CM7, per V7 placement
MDC_ECG_LEAD_CH5	Lead CH5	-
MDC_ECG_LEAD_CS5	Lead CS5	negative: right infraclavicular fossa
MDC_ECG_LEAD_CB5	Lead CB5	negative: low right scapula
MDC_ECG_LEAD_CR5	Lead CR5	-
MDC_ECG_LEAD_ML	Lead ML	ML, modified limb lead, ~ Lead II
MDC_ECG_LEAD_AB1	Lead AB1	AB1 (auxiliary bipolar lead #1)
MDC_ECG_LEAD_AB2	Lead AB2	AB2 (auxiliary bipolar lead #2)
MDC_ECG_LEAD_AB3	Lead AB3	AB3 (auxiliary bipolar lead #3)
MDC_ECG_LEAD_AB4	Lead AB4	AB4 (auxiliary bipolar lead #4)
MDC_ECG_LEAD_ES	Lead ES	EASI™ ES
MDC_ECG_LEAD_AS	Lead AS	EASI AS
MDC_ECG_LEAD_AI	Lead AI	EASI AI
MDC_ECG_LEAD_S	Lead S	EASI upper sternum lead
MDC_ECG_LEAD_dI	Lead dI	derived lead I
MDC_ECG_LEAD_dII	Lead dII	derived lead II
MDC_ECG_LEAD_dIII	Lead dIII	derived lead III
MDC_ECG_LEAD_daVR	Lead daVR	derived lead aVR
MDC_ECG_LEAD_daVL	Lead daVL	derived lead aVL
MDC_ECG_LEAD_daVF	Lead daVF	derived lead aVF
MDC_ECG_LEAD_dV1	Lead dV1	derived lead V1

MDC_ECG_LEAD_dV2	Lead dV2	derived lead V2
MDC_ECG_LEAD_dV3	Lead dV3	derived lead V3
MDC_ECG_LEAD_dV4	Lead dV4	derived lead V4
MDC_ECG_LEAD_dV5	Lead dV5	derived lead V5
MDC_ECG_LEAD_dV6	Lead dV6	derived lead V6
MDC_ECG_LEAD_RL	Lead RL	right leg
MDC_ECG_LEAD_CV5RL	Lead CV5RL	Canine, fifth right ntercostals space near the edge of the sternum at the most curved part of the costal cartilage
MDC_ECG_LEAD_CV6LL	Lead CV6LL	Canine, sixth left ntercostals space near the edge of the sternum at the most curved part of the costal cartilage
MDC_ECG_LEAD_CV6LU	Lead CV6LU	Canine, sixth left ntercostals space at the costochondral junction
MDC_ECG_LEAD_V10	Lead V10	Canine, over dorsal spinous process of the seventh thoracic vertebra

Example of use:

<code code="**MDC_ECG_LEAD_I**" codeSystem="**2.16.840.1.113883.6.24**" codeSystemName="**MDC**" displayName="**Lead I**" />

ECG Annotations

Vocabulary Name: **ECGAnnotationType**

Code System Name: **MDC**

Code System OID: **2.16.840.1.113883.6.24**

The ECG annotations Type vocabulary can be divided in different groups:
- Wave components
- Wave Pacemaker components
- Beat annotations
- Rhythm annotations
- Noise annotations
- Interpretations
- Global ECG Numerics
- Per-Lead ECG Numerics

Code	Display Name	Definition/Description
Wave Component		
MDC_ECG_WAVC_TYPE		Wave Component Type
MDC_ECG_WAVC_PWAVE	P wave	P wave
MDC_ECG_WAVC_PPWAVE	P' wave	P' wave (second deflection in P wave) (P and P' waves have opposite signs)
MDC_ECG_WAVC_PPPWAVE	P'' wave	P'' wave (third deflection in P wave) (P' and P" waves have opposite signs)
MDC_ECG_WAVC_QWAVE	Q wave	Q wave
MDC_ECG_WAVC_QSWAVE	QS wave	QS wave
MDC_ECG_WAVC_RWAVE	R wave	R wave
MDC_ECG_WAVC_RRWAVE	R' wave	R' wave (second deflection in R Wave) (R and R' have same sign)
MDC_ECG_WAVC_RRRWAVE	R'' wave	R'' wave (third deflection in R Wave) (R, R' and R" have same sign)
MDC_ECG_WAVC_NOTCH	Notch	Notch, a slight but distinct change in the direction of a WAVC deflection, contained entirely within that deflection. Typically associated with Q-, R- and/or S-wave.

MDC_ECG_WAVC_SWAVE	S wave	S wave (S and R/R' waves have opposite signs)
MDC_ECG_WAVC_SSWAVE	S' wave	S' wave (second deflection in S Wave) (S' and R'/R" waves have opposite signs)
MDC_ECG_WAVC_SSSWAVE	S'' wave	S'' wave (third deflection in S Wave) (S" and R'/R" waves have opposite signs)
MDC_ECG_WAVC_TWAVE	T wave	T wave
MDC_ECG_WAVC_TTWAVE	T' wave	T' wave (second deflection in T Wave) (T and T' waves have opposite signs)
MDC_ECG_WAVC_UWAVE	U wave	U wave
MDC_ECG_WAVC_DELTA	Delta wave	Delta wave
MDC_ECG_WAVC_IWAVE	I wave	Isoelectric region between global QRS onset and actual onset of QRS in given lead
MDC_ECG_WAVC_KWAVE	K wave	Isoelectric region between actual offset of QRS in given lead and global QRS offset
MDC_ECG_WAVC_JWAVE	J wave	Osborne wave, late and typically upright terminal deflection of QRS complex; amplitude increases as temperature declines. ECG finding typically associated with hypothermia.
MDC_ECG_WAVC_PQRSTWAVE	PQRST wave	Entire Beat (Pon to Toff, excluding U)
MDC_ECG_WAVC_QRSTWAVE	QRST wave	Entire Beat (Qon to Toff, excluding P and U)
MDC_ECG_WAVC_QRSWAVE	QRS wave	Entire QRS (excluding P, T and U)
MDC_ECG_WAVC_TUWAVE	TU wave	TU fused wave
MDC_ECG_WAVC_VFLWAVE	V flutter wave	Ventricular flutter wave (optional) (the appropriate ventricular rhythm call is mandatory)
MDC_ECG_WAVC_AFLWAVE	Atrial flutter wave	Atrial flutter wave (optional) (the appropriate atrial rhythm call is mandatory)
MDC_ECG_WAVC_ISO	Isoelectric point	Isoelectric point or segment
MDC_ECG_WAVC_PRSEG	PR Segment	PR Segment
MDC_ECG_WAVC_STSEG	ST Segment	ST Segment
MDC_ECG_WAVC_STJ	J-point	J-point

MDC_ECG_WAVC_STM	ST meas point	ST measurement point
MDC_ECG_WAVC_ARFCT	Artifact	Isolated qrs-like artifact
MDC_ECG_WAVC_CALP	Calibration pulse	Calibration pulse (individual pulse)
MDC_ECG_WAVC_STCH	ST change	ST change
MDC_ECG_WAVC_TCH	T-wave change	T-wave change
MDC_ECG_WAVC_VAT	Ventricular Activation Time	Ventricular Activation Time also termed the intrinsic (or intrinsicoid) deflection onset to peak of depolarization wave.
Wave Pacemaker Component		
MDC_ECG_WAVP_TYPE		Wave Pacemaker Type
MDC_ECG_WAVP_PACE		Antibradycardia pace
MDC_ECG_WAVP_PACE_ATR		Antibradycardia pace – atrium
MDC_ECG_WAVP_PACE_ATR_R		Antibradycardia pace – right atrium
MDC_ECG_WAVP_PACE_ATR_L		Antibradycardia pace – left atrium
MDC_ECG_WAVP_PACE_V		Antibradycardia pace – ventricular
MDC_ECG_WAVP_PACE_V_R		Antibradycardia pace – right ventricle
MDC_ECG_WAVP_PACE_V_L		Antibradycardia pace – left ventricle
MDC_ECG_WAVP_PACE_EXT		Antibradycardia pace – transthoracic
MDC_ECG_WAVP_ATPACE		Antitachycardia pace
MDC_ECG_WAVP_ATPACE_ATR		Antitachycardia pace – atrium
MDC_ECG_WAVP_ATPACE_V		Antitachycardia pace – ventricle
MDC_ECG_WAVP_ATPACE_EXT		Antitachycardia pace – transthoracic
MDC_ECG_WAVP_CDVS		Cardioversion (low-energy shock)
MDC_ECG_WAVP_CDVS_ATR		Cardioversion (low-energy shock) – atrium
MDC_ECG_WAVP_CDVS_V		Cardioversion (low-energy shock) - ventricle
MDC_ECG_WAVP_CDVS_EXT		Cardioversion (low-energy shock) – transthoracic

MDC_ECG_WAVP_DEFIB		Defibrillation (high-energy shock)
MDC_ECG_WAVP_DEFIB_ATR		Defibrillation (high-energy shock) – atrium
MDC_ECG_WAVP_DEFIB_V		Defibrillation (high-energy shock) – ventricle
MDC_ECG_WAVP_DEFIB_EXT		Defibrillation (high-energy shock) – transthoracic
Beat Annotations		
MDC_ECG_BEAT_TYPE		Beat Annotation Type
MDC_ECG_BEAT		Any beat (unspecified; included in heart rate)
MDC_ECG_BEAT_NORMAL	Normal Beat	Normal beat (sinus beat, normal conduction)
MDC_ECG_BEAT_ABNORMAL	Abnormal Beat	Abnormal beat
MDC_ECG_BEAT_DOMINANT	Dominant Beat	Dominant beat (typically normal, but may not be) (predominant morphology, typically used for ST measurement)
MDC_ECG_BEAT_SV_P_C	Supraventricular premature contraction	Supraventricular premature contraction (atrial or nodal premature beat with normal QRS morphology)
MDC_ECG_BEAT_ATR_P_C	Atrial Premature contraction	Atrial premature contraction (beat)
MDC_ECG_BEAT_JUNC_P_C	Junctional premature contraction	Junctional (nodal) premature contraction
MDC_ECG_BEAT_ATR_P_C_ABER MDC_ECG_BEAT_R	Aberrated atrial premature beat	Aberrated atrial premature beat (Ashman beat) (atrial premature beat with abnormal QRS morphology)
MDC_ECG_BEAT_ATR_PWAVE_B MDC_ECG_BEAT_LK	Non-conducted p-wave	Non-conducted p-wave (blocked)
MDC_ECG_BEAT_V_P_C	Ventricular premature contraction	Ventricular premature contraction (beat)
MDC_ECG_BEAT_V_P_C_FUSION	Fusion of ventricular and normal beat	Fusion of ventricular and normal beat
MDC_ECG_BEAT_V_P_C_RonT	R-on-T premature ventricular beat	R-on-T premature ventricular beat

MDC_ECG_BEAT_SV_ESC		Supraventricular escape beat (least specific)
MDC_ECG_BEAT_ATR_ESC		Atrial escape beat
MDC_ECG_BEAT_JUNC_ESC		Junctional (nodal) escape beat
MDC_ECG_BEAT_V_ESC		Ventricular escape beat
MDC_ECG_BEAT_BB_BLK		bundle branch block beat (unspecified)
MDC_ECG_BEAT_LBB_BLK_COMP		left bundle branch block beat
MDC_ECG_BEAT_LBB_BLK_INCOMP		incomplete left bundle branch block beat
MDC_ECG_BEAT_RBB_BLK_COMP		right bundle branch block beat
MDC_ECG_BEAT_RBB_BLK_INCOMP		incomplete right bundle branch block beat
MDC_ECG_BEAT_BLK_ANT_L_HEMI		left anterior fascicular block beat (common)
MDC_ECG_BEAT_BLK_POS_L_HEMI		left posterior fascicular block beat (rare)
MDC_ECG_BEAT_BLK_BIFASC		bifascicular block beat
MDC_ECG_BEAT_BLK_TRIFASC		trifascicular block beat
MDC_ECG_BEAT_BLK_BILAT		bilateral bundle-branch block beat
MDC_ECG_BEAT_BLK_IVCD		intraventricular conduction disturbance (non-specific block)
MDC_ECG_BEAT_PREX		pre-excitation (least specific)
MDC_ECG_BEAT_WPW_UNK		Wolf-Parkinson-White syndrome (less specific)
MDC_ECG_BEAT_WPW_A		Wolf-Parkinson type A
MDC_ECG_BEAT_WPW_B		Wolf-Parkinson type B
MDC_ECG_BEAT_LGL		Lown-Ganong-Levine syndrome
MDC_ECG_BEAT_PACED		Paced beat (with ventricular capture)
MDC_ECG_BEAT_PACED_FUS		Pacemaker Fusion beat
MDC_ECG_BEAT_UNKNOWN		Unclassifiable beat
MDC_ECG_BEAT_LEARN		Learning (beat during initial learning phase)

Rhythm Annotations

MDC_ECG_RHYTHM_TYPE		Rhythm Annotation Type
MDC_ECG_RHY_SINUS_RHY		Sinus Rhythm
MDC_ECG_RHY_SINUS_NORMAL_RHY		Normal Sinus Rhythm (typically 50 – 90 bpm)
MDC_ECG_RHY_SINUS_BRADY		Sinus Bradycardia (typically < 50 bpm)
MDC_ECG_RHY_SINUS_TACHY		Sinus Tachycardia (typically >90 bpm)
MDC_ECG_RHY_SINUS_ARRHY		Sinus Arrhythmia
MDC_ECG_RHY_RESP_ARRHY		Respiratory Sinus Arrhythmia
MDC_ECG_RHY_NON_RESP_ARRHY		Non-Respiratory Sinus Arrhythmia
MDC_ECG_RHY_WANDP_ARRHY		Wandering Sinus Pacemaker within the sinus node – *gradual P-wave morphology change, relatively constant P-R interval*
MDC_ECG_RHY_WANDPAV_ARRHY		Wandering Pacemaker from the sinus node to (and from) the A-V node - *gradual positive/negative P-wave morphology changes, variable P'-R interval*
MDC_ECG_RHY_ATR_ECT_RHY		Atrial Ectopic Rhythm
MDC_ECG_RHY_ATR_BIGEM		Atrial Bigeminy
MDC_ECG_RHY_ATR_TACHY		Atrial Tachycardia
MDC_ECG_RHY_ATR_TACHY_PAROX		Paroxsysmal Atrial Tachycardia ~ (typically 140 – 220 /m, abrupt)
MDC_ECG_RHY_ATR_TACHY_MF		Multifocal Atrial Tachycardia ~ (typically 100 – 250 /m, "chaotic")

MDC_ECG_RHY_ATR_TACHY_AUTO		Automatic Atrial Tachycardia ~ (typically 150 – 200 /m w/ "warmup")
MDC_ECG_RHY_ATR_FLUT		Atrial flutter ~ (typically 220 – 450 /m) § AV_COND
MDC_ECG_RHY_ATR_FIB		Atrial fibrillation ~ (typically 350 – 650 /m)
MDC_ECG_RHY_SV_ECT_RHY		Supraventricular (atrial or junctional) Ectopic Rhythm
MDC_ECG_RHY_SV_TACHY		Supraventricular Tachycardia (atrial or junctional)
MDC_ECG_RHY_SV_TACHY_PAROX		Supraventricular Paroxsysmal Tachycardia
MDC_ECG_RHY_JUNC_RHY		AV junctional (nodal) rhythm
MDC_ECG_RHY_JUNC_ESC_BEATS		AV junctional (nodal) escape rhythm (typically 40 to 60 bpm)
MDC_ECG_RHY_JUNC_ACCEL		Accelerated AV junctional (nodal) rhythm (typically *active:* 60 to 100 bpm)
MDC_ECG_RHY_JUNC_TACHY		Junctional Tachycardia (typically *active:* >100 bpm)
MDC_ECG_RHY_AV_TACHY_RECIP		AV reciprocating tachycardia
MDC_ECG_RHY_AV_TACHY_REENTRANT		Reentrant AV nodal tachycardia
MDC_ECG_RHY_AV_HEART_BLK_DEG_1		First Degree AV Block - *typically PR interval > 0.2 sec; all P waves conducted*
MDC_ECG_RHY_AV_HEART_BLK_DEG_2		Second Degree AV Block - *typically PR interval may be normal or prolonged; some P-waves do not conduct*

MDC_ECG_RHY_AV_HEART_BLK_DEG_2_I		Second Degree AV Block Type I (Wenckebach) or (Mobitz Type I) - *typically PR interval increases by shorter increments until non-conducted P-wave occurs*
MDC_ECG_RHY_AV_HEART_BLK_DEG_2_II		Second Degree AV Block Type II (Mobitz Type II) – *typically PR intervals are constant until non-conducted P-wave occurs*
MDC_ECG_RHY_AV_HEART_BLK_DEG_3		Third Degree AV Block *(typically complete AV block)*
MDC_ECG_RHY_AV_DISSOC		AV Dissociation
MDC_ECG_RHY_AV_DISSOC_INT		AV dissociation with interference – *typically atrial and ventricular rates are similar with occasional P-waves conducting to the ventricles*
MDC_ECG_RHY_AV_DISSOC_ISO		Isorhythmic AV dissociation – *typically atrial and ventricular rates are the same but P-waves are not conducted*
MDC_ECG_RHY_AV_DISSOC_COMP		Complete AV dissociation – typically *atrial and ventricular rates are different and P-waves are not conducted*
MDC_ECG_RHY_		First Degree SA Block (not observable on surface ECG)
MDC_ECG_RHY_SA_HEART_BLK_DEG_2_I		Second Degree SA Block Type I (Wenckebach)
MDC_ECG_RHY_SA_HEART_BLK_DEG_2_II		Second Degree SA Block Type II
MDC_ECG_RHY_SA_HEART_BLK_DEG_3		Third Degree SA Block *(complete SA block)*
MDC_ECG_RHY_V_RHY		Ventricular rhythm

MDC_ECG_RHY_V_IDIO_RHY		Idioventricular (ventricular escape) rhythm - *typically QRS complexes are wide and appear in a regular rhythm* *- typically 30 to 50 bpm, but may be as low as 15 bpm* *- typically Atrial and ventricular activity are decoupled*
MDC_ECG_RHY_V_PARA		Ventricular Parasystole
MDC_ECG_RHY_V_AIVR		Accelerated idioventricular rhythm *- typically P-waves present, decreasing PR interval, then 'disappear' in QRS complex* *- typically Wide QRS complexes, 60 to 120 bpm; onset is gradual*
MDC_ECG_RHY_V_IDIO_TACHY		Slow Ventricular Tachycardia (Idioventricular Tachycardia)
MDC_ECG_RHY_V_BIGEM		Ventricular Bigeminy
MDC_ECG_RHY_V_TRIGEM		Ventricular Trigeminy
MDC_ECG_RHY_V_P_C_CPLT		Ventricular Couplet
MDC_ECG_RHY_V_P_C_RUN		Ventricular Run
MDC_ECG_RHY_V_TACHY		Ventricular Tachycardia (nonparoxysmal)
MDC_ECG_RHY_V_FLUT		Ventricular Flutter
MDC_ECG_RHY_V_FIB		Ventricular Fibrillation ("chaotic")
MDC_ECG_RHY_V_TACHY_PAROX		Nonsustained Ventricular Tachycardia (paroxysmal)

MDC_ECG_RHY_V_TACHY_MONO		Sustained Monomorphic Ventricular Tachycardia
MDC_ECG_RHY_V_TACHY_POLY		Polymorphic Ventricular Tachycardia
MDC_ECG_RHY_V_TACHY_TDP		Torsades de Pointes Ventricular Tachycardia
MDC_ECG_RHY_PREX		pre-excitation (least specific)
MDC_ECG_RHY_WPW_UNK		Wolf-Parkinson-White syndrome (less specific)
MDC_ECG_RHY_WPW_A		Wolf-Parkinson type A
MDC_ECG_RHY_WPW_B		Wolf-Parkinson type B
MDC_ECG_RHY_LGL		Lown-Ganong-Levine syndrome
MDC_ECG_RHY_ASYSTOLE		Asystole
MDC_ECG_RHY_LHRV		Low Heart Rate Variability
MDC_ECG_RHY_TWA		T-wave alternans
MDC_ECG_RHY_BRADY		Bradycardia (typically < 50 bpm) of any type
MDC_ECG_RHY_CALS		Calibration signal (sustained)
MDC_ECG_RHY_AV_COND		AV conduction ratio
MDC_ECG_RHY_SA_COND		AV conduction ratio
Noise Annotations		
MDC_ECG_NOISE_TYPE	No Noise	Noise Annotation Type
MDC_ECG_NOISE_CLEAN	Noise Clean	No Noise, beat detection and classification can be performed
MDC_ECG_NOISE_MODERATE	Noise Moderate	Noise Level such that beats cannot be classified, but can be detected.
MDC_ECG_NOISE_SEVERE	Noise Severe	Noise Level such that beats cannot be detected or classified.
MDC_ECG_NOISE_NOSIGNAL	No Signal	Indicates that no signal is available due to communication or other loss.
Interpretation		

MDC_ECG_INTERPRETATION	Interpretation	Interpretation
MDC_ECG_INTERPRETATION_STATEMENT	Statement	Interpretation statement
MDC_ECG_INTERPRETATION_COMMENT	Comment	Interpretation comment
MDC_ECG_INTERPRETATION_SUMMARY	Summary	Interpretation summary
Global ECG Numerics		
MDC_ECG_QRS_TYPE		QRS Type
MDC_ECG_QRS_MORPH_NUM		QRS Morphology Class Number
MDC_ECG_VPC_FOCUS_NUM		VPC 'Focus' Number
MDC_ECG_TIME_PD_PP		PP interval, to preceding beat
MDC_ECG_TIME_PD_RR		RR interval, to preceding beat
MDC_ECG_HEART_RATE		Heart rate (method of calculation unspecified)
MDC_ECG_TIME_PD_P		P duration
MDC_ECG_TIME_PD_PQ		PQ interval duration: P onset to QRS onset
MDC_ECG_TIME_PD_PR		PR duration
MDC_ECG_TIME_PD_PQ_SEG		PQ duration
MDC_ECG_TIME_PD_QRS		QRS duration
MDC_ECG_TIME_PD_QT		QT duration
MDC_ECG_TIME_PD_QTc		QTc duration, unspecified correction formula
MDC_ECG_TIME_PD_QTcB		QTc duration using Bazett's correction formula
MDC_ECG_TIME_PD_QTcF		QTc duration using Fridericia's correction formula
MDC_ECG_TIME_PD_QTU		QTU duration, for fused TU wave.
MDC_ECG_TIME_ST_Jxx		Reference time point xx msec after the end of the QRS complex for reporting and _Jxx measurements
MDC_ECG_ANGLE_J_AZIM		Angle, J, Azimuth
MDC_ECG_ANGLE_J_ELEV		Angle, J, Elevation
MDC_ECG_ANGLE_J20_AZIM		Angle, J20, Azimuth
MDC_ECG_ANGLE_J20_ELEV		Angle, J20, Elevation
MDC_ECG_ANGLE_J40_AZIM		Angle, J40, Azimuth

MDC_ECG_ANGLE_J40_ELEV		Angle, J40, Elevation
MDC_ECG_ANGLE_J60_AZIM		Angle, J60, Azimuth
MDC_ECG_ANGLE_J60_ELEV		Angle, J60, Elevation
MDC_ECG_ANGLE_J80_AZIM		Angle, J80, Azimuth
MDC_ECG_ANGLE_J80_ELEV		Angle, J80, Elevation
MDC_ECG_ANGLE_Jxx_AZIM		Angle, Jxx, Azimuth
MDC_ECG_ANGLE_Jxx_ELEV		Angle, Jxx, Elevation
MDC_ECG_ANGLE_P_AZIM		Angle, P, Azimuth
MDC_ECG_ANGLE_P_ELEV		Angle, P, Elevation
MDC_ECG_ANGLE_P_FRONT		Angle, P, Front
MDC_ECG_ANGLE_QRS_AZIM		Angle, QRS, Azimuth
MDC_ECG_ANGLE_QRS_ELEV		Angle, QRS, Elevation
MDC_ECG_ANGLE_QRS_FRONT		Angle, QRS, Front
MDC_ECG_ANGLE_T_ELEV		Angle, T, Elevation
MDC_ECG_ANGLE_T_AZIM		Angle, T, Azimuth
MDC_ECG_ANGLE_T_FRONT		Angle, T, Front
MDC_ECG_ELEC_POTL		Electrical Potential
MDC_ECG_MAG_J_VECT		Magnitude, J, Vector
MDC_ECG_MAG_J20_VECT		Magnitude, J20, Vector
MDC_ECG_MAG_J40_VECT		Magnitude, J40, Vector
MDC_ECG_MAG_J60_VECT		Magnitude, J60, Vector
MDC_ECG_MAG_J80_VECT		Magnitude, J80, Vector
MDC_ECG_MAG_Jxx_VECT		Magnitude, Jxx, Vector
MDC_ECG_MAG_P_FRONT		Magnitude, P, Front
MDC_ECG_MAG_P_VECT		Magnitude, P, Vector
MDC_ECG_MAG_P_VECT_FRONT		Magnitude, P, Vector, Front
MDC_ECG_MAG_P_VECT_HORIZ		Magnitude, P, Vector, Horizontal
MDC_ECG_MAG_P_VECT_SAGI		Magnitude, P, Vector_SAGI
MDC_ECG_MAG_QRS_FRONT		Magnitude, QRS, Front
MDC_ECG_MAG_QRS_VECT		Magnitude, QRS, Vector
MDC_ECG_MAG_QRS_VECT_FRONT		Magnitude, QRS, Vector, Front
MDC_ECG_MAG_QRS_VECT_HORIZ		Magnitude, QRS, Vector_Horizontal
MDC_ECG_MAG_QRS_VECT_SAGI		Magnitude, QRS, Vector_SAGI

MDC_ECG_MAG_T_FRONT		Magnitude, T, Front
MDC_ECG_MAG_T_VECT		Magnitude, T, Vector
MDC_ECG_MAG_T_VECT_FRONT		Magnitude, T, Vector, Front
MDC_ECG_MAG_T_VECT_HORIZ		Magnitude, T, Vector_Horizontal
MDC_ECG_MAG_T_VECT_SAGI		Magnitude, T, Vector_SAGI
Per-Lead ECG Numerics		
MDC_ECG_TIME_START_P_ALL		Start Time, P Wave
MDC_ECG_TIME_START_P_CONFIG		Start Time, P Wave
MDC_ECG_TIME_START_P		Start Time, P Wave
MDC_ECG_TIME_END_P		End Time, P Wave
MDC_ECG_TIME_START_QRS		Start Time, QRS Segment
MDC_ECG_TIME_END_QRS		End Time, QRS Segment
MDC_ECG_TIME_START_T		Start Time, T Wave
MDC_ECG_TIME_PD_VENT_ACTIV		Time Period, Ventrical Activity
MDC_ECG_TIME_PD_P		Time Period, P Wave
MDC_ECG_TIME_PD_P1		Time Period, P1
MDC_ECG_TIME_PD_P2		Time Period, P2
MDC_ECG_TIME_PD_P3		Time Period, P3
MDC_ECG_TIME_PD_PR		Time Period, PR Segment
MDC_ECG_TIME_PD_Q		Time Period, Q Wave
MDC_ECG_TIME_PD_QRS		Time Period, QRS Segment
MDC_ECG_TIME_PD_QT		Time Period, QT Segment
MDC_ECG_TIME_PD_R_1		Time Period, R1
MDC_ECG_TIME_PD_R_2		Time Period, R2
MDC_ECG_TIME_PD_R_3		Time Period, R3
MDC_ECG_TIME_PD_S_1		Time Period, S1
MDC_ECG_TIME_PD_S_2		Time Period, S2
MDC_ECG_TIME_PD_S_3		Time Period, S3
MDC_ECG_TIME_PD_PP		Time Period, PP
MDC_ECG_TIME_PD_RR		Time Period, RR
MDC_ECG_TIME_PD_PQ		Time Period, PQ
MDC_ECG_TIME_PD_PQ_SEG		Time Period, PQ
MDC_ECG_TIME_PD_QTc		Time Period, QT (Corrected)

MDC_ECG_TIME_PD_QTcB		Time Period, QT (Corrected) using Bazett's correction formula
MDC_ECG_TIME_PD_QTcF		Time Period, QT (Corrected) using Fridericia's correction formula
MDC_ECG_TIME_PD_QTU		Time Period, QTU
MDC_ECG_ELEC_POTL		Electrical Potential
MDC_ECG_ELEC_POTL_I		Electrical Potential; Lead I
MDC_ECG_ELEC_POTL_II		Electrical Potential; Lead II
MDC_ECG_ELEC_POTL_V1		Electrical Potential; Lead V1
MDC_ECG_ELEC_POTL_V2		Electrical Potential; Lead V2
MDC_ECG_ELEC_POTL_V3		Electrical Potential; Lead V3
MDC_ECG_ELEC_POTL_V4		Electrical Potential; Lead V4
MDC_ECG_ELEC_POTL_V5		Electrical Potential; Lead V5
MDC_ECG_ELEC_POTL_V6		Electrical Potential; Lead V6
MDC_ECG_ELEC_POTL_V7		Electrical Potential; Lead V7
MDC_ECG_ELEC_POTL_V3R		Electrical Potential; Lead V3R
MDC_ECG_ELEC_POTL_V4R		Electrical Potential; Lead V4R
MDC_ECG_ELEC_POTL_V5R		Electrical Potential; Lead V5R
MDC_ECG_ELEC_POTL_V6R		Electrical Potential; Lead V6R
MDC_ECG_ELEC_POTL_V7R		Electrical Potential; Lead V7R
MDC_ECG_ELEC_POTL_VX		Electrical Potential; Lead X
MDC_ECG_ELEC_POTL_VY		Electrical Potential; Lead Y
MDC_ECG_ELEC_POTL_VZ		Electrical Potential; Lead Z
MDC_ECG_ELEC_POTL_CC5		Electrical Potential; Lead CC5, per V5 and V5R placement
MDC_ECG_ELEC_POTL_CM5		Electrical Potential; Lead CM5, per V5 placement
MDC_ECG_ELEC_POTL_LA		Electrical Potential; Lead Left Arm
MDC_ECG_ELEC_POTL_RA		Electrical Potential; Lead Right Arm
MDC_ECG_ELEC_POTL_LL		Electrical Potential; Lead Left Leg
MDC_ECG_ELEC_POTL_fI		Electrical Potential; Lead I
MDC_ECG_ELEC_POTL_fE		Electrical Potential; Lead E
MDC_ECG_ELEC_POTL_fC		Electrical Potential; Lead C

MDC_ECG_ELEC_POTL_fA		Electrical Potential; Lead A
MDC_ECG_ELEC_POTL_fM		Electrical Potential; Lead M
MDC_ECG_ELEC_POTL_fF		Electrical Potential; Lead F
MDC_ECG_ELEC_POTL_fH		Electrical Potential; Lead H
MDC_ECG_ELEC_POTL_III		Electrical Potential; Lead III
MDC_ECG_ELEC_POTL_AVR		Electrical Potential; Lead aVR, augmented voltage, right
MDC_ECG_ELEC_POTL_AVL		Electrical Potential; Lead aVL, augmented voltage, left
MDC_ECG_ELEC_POTL_AVF		Electrical Potential; Lead aVF, augmented voltage, foot
MDC_ECG_ELEC_POTL_AVRneg		Electrical Potential; Lead – aVR
MDC_ECG_ELEC_POTL_V8		Electrical Potential; Lead V8
MDC_ECG_ELEC_POTL_V9		Electrical Potential; Lead V9
MDC_ECG_ELEC_POTL_V8R		Electrical Potential; Lead V8R
MDC_ECG_ELEC_POTL_V9R		Electrical Potential; Lead V9R
MDC_ECG_ELEC_POTL_D		Electrical Potential; Lead D (Nebb – Dorsal)
MDC_ECG_ELEC_POTL_A		Electrical Potential; Lead A (Nebb – Anterior)
MDC_ECG_ELEC_POTL_J		Electrical Potential; Lead J (Nebb – Inferior)
MDC_ECG_ELEC_POTL_DEFIB		Electrical Potential; Lead Defibrillator lead: anterior-lateral
MDC_ECG_ELEC_POTL_EXTERN		Electrical Potential; Lead External pacing lead; anterior-posterior
MDC_ECG_ELEC_POTL_A1		Electrical Potential; Lead A1 (Auxiliary unipolar lead #1)
MDC_ECG_ELEC_POTL_A2		Electrical Potential; Lead A2 (Auxiliary unipolar lead #2)
MDC_ECG_ELEC_POTL_A3		Electrical Potential; Lead A3 (Auxiliary unipolar lead #3)
MDC_ECG_ELEC_POTL_A4		Electrical Potential; Lead A4 (Auxiliary unipolar lead #4)
MDC_ECG_ELEC_POTL_C		Electrical Potential; Lead Chest
MDC_ECG_ELEC_POTL_V		Electrical Potential; Lead V

MDC_ECG_ELEC_POTL_VR		Electrical Potential; Lead VR, nonaugmented voltage, vector of RA
MDC_ECG_ELEC_POTL_VL		Electrical Potential; Lead VL, nonaugmented voltage, vector of RA
MDC_ECG_ELEC_POTL_VF		Electrical Potential; Lead VF, nonaugmented voltage, vector of RA
MDC_ECG_ELEC_POTL_MCL		Electrical Potential; Lead Modified chest lead (left arm indifferent)
MDC_ECG_ELEC_POTL_MCL1		Electrical Potential; Lead MCL1, per V1 placement
MDC_ECG_ELEC_POTL_MCL2		Electrical Potential; Lead MCL2, per V2 placement
MDC_ECG_ELEC_POTL_MCL3		Electrical Potential; Lead MCL3, per V3 placement
MDC_ECG_ELEC_POTL_MCL4		Electrical Potential; Lead MCL4, per V4 placement
MDC_ECG_ELEC_POTL_MCL5		Electrical Potential; Lead MCL5, per V5 placement
MDC_ECG_ELEC_POTL_MCL6		Electrical Potential; Lead MCL6, per V6 placement
MDC_ECG_ELEC_POTL_CC		Electrical Potential; Lead Chest lead (symmetric placement)
MDC_ECG_ELEC_POTL_CC1		Electrical Potential; Lead CC1, per V1 and V1R placement
MDC_ECG_ELEC_POTL_CC2		Electrical Potential; Lead CC2, per V2 and V2R placement
MDC_ECG_ELEC_POTL_CC3		Electrical Potential; Lead CC3, per V3 and V3R placement
MDC_ECG_ELEC_POTL_CC4		Electrical Potential; Lead CC4, per V4 and V4R placement
MDC_ECG_ELEC_POTL_CC6		Electrical Potential; Lead CC6, per V6 and V6R placement
MDC_ECG_ELEC_POTL_CC7		Electrical Potential; Lead CC7, per V7 and V7R placement

MDC_ECG_ELEC_POTL_CM		Electrical Potential; Lead Chest-manubrium
MDC_ECG_ELEC_POTL_CM1		Electrical Potential; Lead CM1, per V1 placement
MDC_ECG_ELEC_POTL_CM2		Electrical Potential; Lead CM2, per V2 placement
MDC_ECG_ELEC_POTL_CM3		Electrical Potential; Lead CM3, per V3 placement
MDC_ECG_ELEC_POTL_CM4		Electrical Potential; Lead CM4, per V4 placement
MDC_ECG_ELEC_POTL_CM6		Electrical Potential; Lead CM6, per V6 placement
MDC_ECG_ELEC_POTL_CM7		Electrical Potential; Lead CM7, per V7 placement
MDC_ECG_ELEC_POTL_CH5		Electrical Potential; -- (CH5)
MDC_ECG_ELEC_POTL_CS5		Electrical Potential; Negative: right infraclavicular fossa
MDC_ECG_ELEC_POTL_CB5		Electrical Potential; Negative: low right scapula
MDC_ECG_ELEC_POTL_CR5		Electrical Potential; -- (CR5)
MDC_ECG_ELEC_POTL_ML		Electrical Potential; Lead ML, modified limb lead, - Lead II
MDC_ECG_ELEC_POTL_AB1		Electrical Potential; Lead AB1 (auxiliary bipolar lead #1)
MDC_ECG_ELEC_POTL_AB2		Electrical Potential; Lead AB2 (auxiliary bipolar lead #2)
MDC_ECG_ELEC_POTL_AB3		Electrical Potential; Lead AB3 (auxiliary bipolar lead #3)
MDC_ECG_ELEC_POTL_AB4		Electrical Potential; Lead AB4 (auxiliary bipolar lead #4)
MDC_ECG_ELEC_POTL_ES		Electrical Potential; Lead EASI™ ES
MDC_ECG_ELEC_POTL_AS		Electrical Potential; Lead EASI AS
MDC_ECG_ELEC_POTL_AI		Electrical Potential; Lead EASI AI
MDC_ECG_ELEC_POTL_S		Electrical Potential; Lead EASI upper sternum lead
MDC_ECG_ELEC_POTL_dI		Electrical Potential; Lead derived, I
MDC_ECG_ELEC_POTL_dII		Electrical Potential; Lead derived, II

MDC_ECG_ELEC_POTL_dIII		Electrical Potential; Lead derived, III
MDC_ECG_ELEC_POTL_daVR		Electrical Potential; Lead derived, aVR
MDC_ECG_ELEC_POTL_daVL		Electrical Potential; Lead derived, aVL
MDC_ECG_ELEC_POTL_daVF		Electrical Potential; Lead derived, aVF
MDC_ECG_ELEC_POTL_dV1		Electrical Potential; Lead derived, V1
MDC_ECG_ELEC_POTL_dV2		Electrical Potential; Lead derived, V2
MDC_ECG_ELEC_POTL_dV3		Electrical Potential; Lead derived, V3
MDC_ECG_ELEC_POTL_dV4		Electrical Potential; Lead derived, V4
MDC_ECG_ELEC_POTL_dV5		Electrical Potential; Lead derived, V5
MDC_ECG_ELEC_POTL_dV6		Electrical Potential; Lead derived, V6
MDC_ECG_ELEC_POTL_RL		Electrical Potential; Lead Right leg
MDC_ECG_ELEC_POTL_ST_20		Electrical Potential, ST 20 point
MDC_ECG_ELEC_POTL_ST_40		Electrical Potential, ST 20 point
MDC_ECG_ELEC_POTL_ST_60		Electrical Potential, ST 20 point
MDC_ECG_ELEC_POTL_ST_80		Electrical Potential, ST 20 point
MDC_ECG_ELEC_POTL_R_1		Electrical Potential, R1
MDC_ECG_ELEC_POTL_R_2		Electrical Potential, R2
MDC_ECG_ELEC_POTL_R_3		Electrical Potential, R3
MDC_ECG_ELEC_POTL_S_1		Electrical Potential, S1
MDC_ECG_ELEC_POTL_S_2		Electrical Potential, S2
MDC_ECG_ELEC_POTL_S_3		Electrical Potential, S3
MDC_ECG_AMPL_J		Amplitude, J point
MDC_ECG_AMPL_P_MAX		Amplitude, P, Maximum
MDC_ECG_AMPL_P_MIN		Amplitude, P, Minimum
MDC_ECG_AMPL_P3		Amplitude, P3
MDC_ECG_AMPL_Q		Amplitude, Q

MDC_ECG_AMPL_R		Amplitude, R
MDC_ECG_AMPL_S		Amplitude, S
MDC_ECG_AMPL_T_MAX		Amplitude, T, Maximum
MDC_ECG_AMPL_T_MIN		Amplitude, T, Minimum
MDC_ECG_AMPL_ST		Amplitude, ST
MDC_ECG_INTEGRAL_P		Integral, P
MDC_ECG_AREA_P		Area, P

Control variable

Vocabulary Name:	**ECGControlVariable**
Code System Name:	**ActCode**
Code System OID:	**2.16.840.1.113883.5.4**

This vocabulary includes the **ECGControlVariableMDC** vocabulary and it has not codes.

Control variable

Vocabulary Name:	**ECGControlVariableMDC**
Code System Name:	**MDC**
Code System OID:	**2.16.840.1.113883.6.24**

Code	Display Name / Description
MDC_ECG_CTL_VBL	Generic control variable
MDC_ECG_CTL_VBL_SAMPLE_RATE	Sample rate
MDC_ECG_CTL_VBL_SENSITIVITY	Sensitivity
MDC_ECG_CTL_VBL_ZERO_OFFSET	Zero offset
MDC_ECG_CTL_VBL_VALID_RANGE	Valid range
MDC_ECG_CTL_VBL_PAD_VALUE	Pad value
MDC_ECG_CTL_VBL_TIME_SKEW	Time skew
MDC_ECG_CTL_VBL_SAMPLE_SKEW	Sample skew
MDC_ECG_CTL_VBL_TIME_OFFSET	Time offset
MDC_ECG_CTL_VBL_QTC_METHOD	QTc correction method
MDC_ECG_CTL_VBL_ATTR_FILTER_LOW_PASS	Low pass filter
MDC_ECG_CTL_VBL_ATTR_FILTER_CUTOFF_FREQ	Low pass filter cutoff freq
MDC_ECG_CTL_VBL_ATTR_FILTER_HIGH_PASS	High pass filter
MDC_ECG_CTL_VBL_ATTR_FILTER_ORDER	High pass filter order
MDC_ECG_CTL_VBL_ATTR_FILTER_DESCRIPTION	High pass filter description
MDC_ECG_CTL_VBL_ATTR_FILTER_NOTCH	Notch filter
MDC_ECG_CTL_VBL_ATTR_FILTER_NOTCH_FREQ	Notch filter frequency

MDC_ECG_CTL_VBL_ATTR_FILTER_NOTCH_BANDWIDTH	Notch filter bandwidth
MDC_ECG_CTL_VBL_ATTR_FILTER_DESCRIPTION	Notch filter description
MDC_ECG_CTL_VBL_BASELINE	Baseline
MDC_ECG_CTL_VBL_BASELINE_DESC	Baseline description
MDC_ECG_CTL_VBL_BASELINE_ORDER	Baseline order
MDC_ECG_CTL_VBL_INTERPOLATOR	Interpolator
MDC_ECG_CTL_VBL_INTERPOLATOR_SRC_SAMP_RATE	Interpolator source sample rate
MDC_ECG_CTL_VBL_INTERPOLATOR_DESC	Interpolator description
MDC_ECG_CTL_VBL_INTERPOLATOR_ORDER	Interpolator order
MDC_ECG_CTL_VBL_INTERPOLATOR_SNR	Interpolator snr
MDC_ECG_CTL_VBL_DISPLAYED_SIZE	Displayed size
MDC_ECG_CTL_VBL_DISPLAYED_COLOR	Displayed color
MDC_ECG_CTL_VBL_DISPLAYED_SWEEP_RATE	Displayed sweep rate
MDC_ECG_CTL_VBL_ATTR_RHTYHM	Rhythm attribute
MDC_ECG_CTL_VBL_ATTR_AV_COND	Rhythm attribute AV_Cond
MDC_ECG_CTL_VBL_ATTR_SA_COND	Rhythm attribute SA_Cond
MDC_ECG_CTL_VBL_ATTR_RHYTHM_CRITERIA	Rhythm criteria attribute
MDC_ECG_CTL_VBL_ATTR_RHYTHM_CODE	Rhythm criteria attribute code
MDC_ECG_CTL_VBL_ATTR_RATE_LIMIT_HIGH_GT	Rhythm criteria attribute rate hi GT limit
MDC_ECG_CTL_VBL_ATTR_RATE_LIMIT_HIGH_GE	Rhythm criteria attribute rate hi GE limit
MDC_ECG_CTL_VBL_ATTR_RATE_LIMIT_LOW_LT	Rhythm criteria attribute rate lo LT limit
MDC_ECG_CTL_VBL_ATTR_RATE_LIMIT_LOW_LE	Rhythm criteria attribute rate lo LE limit
MDC_ECG_CTL_VBL_ATTR_RATE_ LIMIT_LOW_GT	Rhythm criteria attribute rate lo GT limit
MDC_ECG_CTL_VBL_ATTR_RATE_ LIMIT_LOW_GE	Rhythm criteria attribute rate lo GE limit
MDC_ECG_CTL_VBL_ATTR_RATE_ LIMIT_HGH_LT	Rhythm criteria attribute rate hi LT limit
MDC_ECG_CTL_VBL_ATTR_RATE_ LIMIT_HIGH_LE	Rhythm criteria attribute rate hi LE limit

Example of use:

```
<code code="MDC_ATTR_FILTER_LOW_PASS" codeSystem="2.16.840.1.113883.6.24"
codeSystemName="MDC" displayName="Low Pass Filter" />
```

Vocabularies not yet defined

As of today, a group of vocabularies has not been formally established and/or completed.

The following codes may change in future.

Reason of the ECG

Vocabulary Name: Not yet defined

Code System Name: Not yet defined

Code System OID: Not yet defined

As of this guide's publishing, no vocabulary has been formally established for these codes. Suggested values are:

Code	Display Name	Definition/Description
PER_PROTOCOL		The protocol specified that a measurement be performed at this point in the trial.
NOT_IN_PROTOCOL		The protocol did not specify that a measurement be performed at this point in the trial. However, a measurement was taken (for unspecified reasons).
IN_PROTOCOL_WRONG_EVENT		The protocol specified that a measurement be performed, but it was performed at the wrong point in the trial.

Example of use:

<reasonCode code="PER_PROTOCOL" codeSystem="" />

Confidentiality of the ECG

Vocabulary Name: Not yet defined

Code System Name: Not yet defined

Code System OID: Not yet defined

As of this guide's publishing, no vocabulary has been formally established for these codes. Suggested values are from the CDISC lab model:

Code	Display Name	Definition/Description
S	Blinded to sponsor	Blinded to sponsor
I	Blinded to investigator	Blinded to investigator
B	Blinded to sponsor and investigator	Blinded to sponsor and investigator
C	Custom blinding	Custom blinding

Example of use:

<confidentialityCode code="S" codeSystem="" displayName="**Blinded to sponsor**" />

Reason of the Time Point Event

<table>
<tr><td>Vocabulary Name:</td><td>Not yet defined</td></tr>
<tr><td>Code System Name:</td><td>Not yet defined</td></tr>
<tr><td>Code System OID:</td><td>Not yet defined</td></tr>
</table>

As of this guide's publishing, no vocabulary has been formally established for these codes. Suggested values are from the CDISC lab model VisitType field:

Code	Display Name	Definition/Description
S	Scheduled	Scheduled; this was a planned visit according to the protocol.
U	Unscheduled	unscheduled; this visit was not planned

Example of use:

<reasoncode code="S" codeSystem="" />

Subject role

Vocabulary Name: **ResearchSubjectRoleBasis**

Code System Name: **RoleCode**

Code System OID: **2.16.840.1.113883.5.111**

As of today, HL7 has defined this vocabulary; however the associated codes have not yet been specified.

Suggested values are:

Code	Display Name	Definition/Description
SCREENING		The subject was being screened for participation in the trial but had not yet been enrolled.
ENROLLED		The subject was enrolled in the trial.

Example of use:

```
<code code="SCREENING" codeSystem="2.16.840.1.113883.5.111"
codeSystemName="ResearchSubjectRoleBasis" />
```

Device code

<table>
<tr><td colspan="3">
Vocabulary Name: **EntityCode**

Code System Name: **EntityCode**

Code System OID: **2.16.840.1.113883.5.1061**

As of today, the EntityCode vocabulary is defined as the vocabulary for the device code, but this code system has not yet a set of codes specific for the ECG recorders.

The suggest values are:
</td></tr>
<tr><td>**Code**</td><td>**Display Name**</td><td>**Definition/Description**</td></tr>
<tr><td>12LEAD_ELECTROCARDIOGRAPH</td><td></td><td></td></tr>
<tr><td>12LEAD_HOLTER</td><td></td><td></td></tr>
<tr><td colspan="3">
Example of use:

<code code="**12LEAD_ELECTROCARDIOGRAPH**" codeSystem="" codeSystemName="" />
</td></tr>
</table>

Secondary performer function

Vocabulary Name: **ParticipationFunction**

Code System Name: **ParticipationFunction**

Code System OID: **2.16.840.1.113883.5.88**

As of today, HL7 has defined this vocabulary, however the associated codes for secondary performer functions in the context of a clinical trial have not been established.

The suggest values are:

Code	Display Name	Definition/Description
HOLTER_HOOKUP_TECH		
HOLTER_ANALYST		
ELECTROCARDIOGRAPH_TECH		

Example of use:

<functionCode code="ELECTROCARDIOGRAPH_TECH" codeSystem="" />

Annotation Methods

Vocabulary Name:	**ObservationMethod**
Code System Name:	**ObservationMethod**
Code System OID:	**2.16.840.1.113883.5.84**

As of today, HL7 has defined this vocabulary, however the associated codes for the context of a clinical trial have not been established.

The suggest values are:

Code	Display Name	Definition/Description

Example of use:

<methodCode code="" codeSystem="" />