Status	Letter Ballot
Date of Last Update	2024/01/14
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Submission Date	2023/08/28

Correction Number CP-2335
Log Summary: Clinical Trial Identifiers need Issuers and may be multiple
Name of Standard PS3.3, PS3.6, PS3.15
Rationale for Correction: Identifiers need issuers in order to define their scope. Multiple identifiers may be needed the same entity, esp. the protocol, à la Other Patient IDs Sequence. A specific use case is the need to identify images from a specific trial or experiment by its well-known research collection ID as used in a shared data repository, as well as the Digital Object Identifier (DOI) for that collection.]
Correction Wording:

*Amend DICOM PS3.3 as follows (changes to existing text are bold and **underlined** for additions and **~~struckthrough~~** for removals):*

C.7.1.3 Clinical Trial Subject Module

Table C.7-2b. Clinical Trial Subject Module Attributes

Attribute Name	Tag	Type	Attribute Description
Clinical Trial Sponsor Name	(0012,0010)	1	The name of the clinical trial or research sponsor. See Section C.7.1.3.1.1.
Clinical Trial Protocol ID	(0012,0020)	1	Identifier for the **~~noted~~** protocol. See Section C.7.1.3.1.2.
Issuer of Clinical Trial Protocol ID	**(gggg,eee1)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Protocol ID.**
Other Clinical Trial Protocol IDs Sequence	**(gggg,eee5)**	**3**	**Identification numbers or codes used to identify the protocol.** **One or more Items are permitted in this Sequence.**
>Clinical Trial Protocol ID	**(0012,0020)**	**1**	**Identifier for the protocol. See Section C.7.1.3.1.2.**
>Issuer of Clinical Trial Protocol ID	**(gggg,eee1)**	**1**	**Identifier of the Assigning Authority that issued the Clinical Trial Protocol ID.**
Clinical Trial Protocol Name	(0012,0021)	2	The name of the clinical trial or research protocol. See Section C.7.1.3.1.3.
Clinical Trial Site ID	(0012,0030)	2	The identifier of the site responsible for submitting clinical trial or research data. See Section C.7.1.3.1.4.
Issuer of Clinical Trial Site ID	**(gggg,eee2)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Site ID.**
Clinical Trial Site Name	(0012,0031)	2	Name of the site responsible for submitting clinical trial or research data. See Section C.7.1.3.1.5
Clinical Trial Subject ID	(0012,0040)	1C	The assigned identifier for the clinical trial or research subject. See Section C.7.1.3.1.6. Shall be present if Clinical Trial Subject Reading ID (0012,0042) is absent. May be present otherwise.
Issuer of Clinical Trial Subject ID	**(gggg,eee3)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Subject ID.**
Clinical Trial Subject Reading ID	(0012,0042)	1C	Identifies the subject for blinded evaluations. Shall be present if Clinical Trial Subject ID (0012,0040) is absent. May be present otherwise. See Section C.7.1.3.1.7.
Issuer of Clinical Trial Subject Reading ID	**(gggg,eee4)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Subject Reading ID.**
Clinical Trial Protocol Ethics Committee Name	(0012,0081)	1C	Name of the Ethics Committee or Institutional Review Board (IRB) or Institutional Animal Care and Use Committees (IACUC) responsible for approval of the Clinical Trial or research. Required if Clinical Trial Protocol Ethics Committee Approval Number (0012,0082) is present.
Clinical Trial Protocol Ethics Committee Approval Number	(0012,0082)	3	Approval number issued by committee described in Clinical Trial Protocol Ethics Committee Name (0012,0081).

C.7.1.3.1 Clinical Trial Subject Module Attribute Descriptions

Identification of subjects in clinical trials or research generally requires a combination of the following four Attributes:

1. Clinical Trial Sponsor Name (0012,0010),
2. Clinical Trial Protocol ID (0012,0020),

3. Clinical Trial Subject ID (0012,0040) (or Clinical Trial Subject Reading ID (0012,0042) for blinded evaluations), and

4. Clinical Trial Site ID (0012,0030).

For trials in which subject identifiers are unique within the scope of the Clinical Trial Protocol (e.g., if subject identifiers are centrally assigned or contain the site identifier) the Clinical Trial Site ID (0012,0030) is not required to identify subjects.

C.7.1.3.1.1 Clinical Trial Sponsor Name

The Clinical Trial Sponsor Name (0012,0010) identifies the entity responsible for conducting the clinical trial or research and for defining the Clinical Trial Protocol ID (0012,0020).

C.7.1.3.1.2 Clinical Trial Protocol ID

The Clinical Trial Protocol ID (0012,0020) is the number or character sequence used by the Clinical Trial Sponsor to uniquely identify the investigational protocol in which the subject has been enrolled.

Note

If more than one identifier is needed to identify the protocol, one may be conveyed Clinical Trial Protocol ID (0012,0020) in the top level dataset and the others included in Other Clinical Trial Protocol IDs Sequence (gggg,eee5), and the source of each distinguished by their Issuer of Clinical Trial Protocol ID (gggg,eee1).

Here is an example of identifying a completed trial whose data has been shared and assigned a digital object identifier:

Clinical Trial Protocol ID (0012,0020) = "TCGA-GBM"

Issuer of Clinical Trial Protocol ID (gggg,eee1) = "NCI"

Other Clinical Trial Protocol IDs Sequence (gggg,eee5)

>Clinical Trial Protocol ID (0012,0020) = "doi:10.7937/K9/TCIA.2016.RNYFUYE9"

>Issuer of Clinical Trial Protocol ID (gggg,eee1) = "DOI"

Here is an example of identifying a clinical trial that is potentially ongoing and not yet published or shared, and has multiple (primary and secondary) identifiers from the same issuer (which are enumerated but not otherwise distinguished from each other):

Clinical Trial Protocol ID (0012,0020) = "D6940C00002"

Issuer of Clinical Trial Protocol ID (gggg,eee1) = "NCI"

Other Clinical Trial Protocol IDs Sequence (gggg,eee5)

>Clinical Trial Protocol ID (0012,0020) = "NCI-2018-00805"

>Issuer of Clinical Trial Protocol ID (gggg,eee1) = "NCI"

>Clinical Trial Protocol ID (0012,0020) = "135803"

>Issuer of Clinical Trial Protocol ID (gggg,eee1) = "NCI"

>Clinical Trial Protocol ID (0012,0020) = "2017-002451-28"

>Issuer of Clinical Trial Protocol ID (gggg,eee1) = "NCI"

>Clinical Trial Protocol ID (0012,0020) = "NCT03423628"

>Issuer of Clinical Trial Protocol ID (gggg,eee1) = "ClinicalTrials.gov"

C.7.1.3.1.3 Clinical Trial Protocol Name

The Clinical Trial Protocol Name (0012,0021) contains the title of the investigational protocol in which the subject has been enrolled.

Note

It is recommended that the phase of the clinical trial or research be noted in the Clinical Trial Protocol Name, if applicable.

C.7.1.3.1.4 Clinical Trial Site ID

The Clinical Trial Site ID (0012,0030) is the identification number or character string (issued by the entity identified by the Clinical Trial Sponsor Name (0012,0010)) used to identify the site responsible for submitting clinical trial or research data.

C.7.1.3.1.5 Clinical Trial Site Name

The Clinical Trial Site Name (0012,0031) is a character string used to identify the site responsible for submitting clinical trial or research data.

C.7.1.3.1.6 Clinical Trial Subject ID

The Clinical Trial Subject ID (0012,0040) identifies the subject within the investigational protocol specified by Clinical Trial Protocol ID (0012,0020).

Note

The Clinical Trial Subject ID (0012,0040) may, but is not required to be, the same as Patient ID (0010,0020).

C.7.1.3.1.7 Clinical Trial Subject Reading ID

The Clinical Trial Subject Reading ID (0012,0042) identifies the subject in the context of blinded evaluations.

C.7.2.3 Clinical Trial Study Module

Table C.7-4b. Clinical Trial Study Module Attributes

Attribute Name	Tag	Type	Attribute Description
Clinical Trial Time Point ID	(0012,0050)	2	An identifier specifying the one or more Studies that are grouped together as a clinical time point or submission in a clinical trial or research. See Section C.7.2.3.1.1.
Issuer of Clinical Trial Time Point ID	**(gggg,eee5)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Time Point ID.**
Clinical Trial Time Point Description	(0012,0051)	3	A description of a set of one or more Studies that are grouped together to represent a clinical time point or submission in a clinical trial or research. See Section C.7.2.3.1.1.
Clinical Trial Time Point Type Code Sequence	(0012,0054)	3	A pre-defined type of a set of one or more Studies that are grouped together to represent a clinical time point or submission in a clinical trial or research. See Section C.7.2.3.1.1. One or more Items are permitted in this Sequence.
>Include ???			*BCID 6146 "Time Point Type".*
Longitudinal Temporal Offset from Event	(0012,0052)	3	An offset in days from a particular event of significance. May be fractional. In the context of a clinical trial, this is often the days since enrollment, or the baseline imaging Study.

Attribute Name	Tag	Type	Attribute Description
Longitudinal Temporal Event Type	(0012,0053)	1C	The type of event to which Longitudinal Temporal Offset from Event (0012,0052) is relative. **Defined Terms:** **ENROLLMENT** Relative to enrollment of the subject in the research activity or clinical trial. **BASELINE** Relative to the baseline imaging Study. Required if Longitudinal Temporal Offset from Event (0012,0052) is present.
Consent for Clinical Trial Use Sequence	(0012,0083)	3	A Sequence that conveys information about consent for Clinical Trial or research use of the Composite Instances within this Study. One or more Items are permitted in this Sequence. See Section C.7.2.3.1.2.
>Distribution Type	(0012,0084)	1C	The type of distribution for which consent to distribute has been granted. **Defined Terms:** **NAMED_PROTOCOL** **RESTRICTED_REUSE** **PUBLIC_RELEASE** See Section C.7.2.3.1.2. Required if Consent for Distribution Flag (0012,0085) equals YES or WITHDRAWN.
>Clinical Trial Protocol ID	(0012,0020)	1C	The identifier of the protocol for which consent to distribute has been granted. Required if Distribution Type (0012,0084) is NAMED_PROTOCOL and the protocol is not that which is specified in Clinical Trial Protocol ID (0012,0020) in the Clinical Trial Subject Module.
>Issuer of Clinical Trial Protocol ID	**(gggg,eee1)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Protocol ID.**
>Consent for Distribution Flag	(0012,0085)	1	Whether or not consent to distribute has been granted for the purpose described in Distribution Type (0012,0084). **Enumerated Values:** **NO** **YES** **WITHDRAWN** See Section C.7.2.3.1.2. **Note** Under some circumstances, consent may be withdrawn. The purpose of encoding this is to warn receiving systems that further distribution may not be appropriate, but no semantics are defined by the Standard for what action is appropriate under such circumstances, such as what to do with previously received images that had a value of YES.

C.7.2.3.1 Clinical Trial Study Module Attribute Descriptions

C.7.2.3.1.1 Clinical Trial Time Point

The Clinical Trial Time Point ID (0012,0050) Attribute identifies an imaging Study within the context of an investigational protocol. This Attribute is used to define a set of Studies that are grouped together as a clinical time point or data submission in a clinical trial or research. The Clinical Trial Time Point Description (0012,0051) Attribute can be used to give a description of the Clinical Trial Time Point to which the set of Studies belongs. Clinical Trial Time Point Type Code Sequence (0012,0054) can be used to specify one or more pre-defined type of time point from a standard lexicon; more than one type is permitted, e.g., a time point may be "posttreatment" as well as "unscheduled" or "nadir", etc.

C.7.2.3.1.2 Consent For Clinical Trial Use Sequence

For applications such as clinical trials or research, the distribution of Composite Instances in Studies, whether containing identifying information or partially or completely de-identified, may need to be controlled. Permission for distribution is usually granted under the control of the Patient (through informed consent), the ethics committee or institutional review board responsible for the Study, and the sponsor of the Study through contractual means. The Consent for Clinical Trial Use Sequence (0012,0083) is intended to encode the result of the consent process to allow appropriate subsequent handling of the Instances.

The Defined Terms for Distribution Type (0012,0084) mean that consent has been issued to distribute for the following purposes:

Defined Terms:

NAMED_PROTOCOL conducting the protocol named in Clinical Trial Protocol ID (0012,0020)

RESTRICTED_REUSE re-use for restricted purposes (not specified here) other than those for which the Instances were originally created

PUBLIC_RELEASE release to the general public for re-use without restriction

Note

1. There is no intent to convey in this Sequence further details of the often complex consent and approval process. Further information about the protocol and ethics committee may be found in the Clinical Trials Modules, if present.

2. There is no identification of an individual responsible for the approval or granting consent, since in the case of a clinical trial or research subject granting informed consent, the presence of this information would breach de-identification requirements.

3. Multiple Sequence Items may be present; for example a Study may be approved for distribution for conducting multiple explicitly named protocols.

4. Whether or not the Instances have been adequately de-identified for any particular purpose of distribution is not defined by the Attributes in the Consent for Clinical Trial Use Sequence (0012,0083). Other Attributes address this, such as Patient Identity Removed (0012,0062), De-identification Method (0012,0063), De-identification Method Code Sequence (0012,0064) and Burned In Annotation (0028,0301). See also Annex E “Attribute Confidentiality Profiles (Normative)” in PS3.15.

5. It is possible that the list of Defined Terms for Distribution Type (0012,0084) may be extended in future for other purposes, not necessarily related to the conduct of clinical trials or research.

C.7.3.2 Clinical Trial Series Module

Table C.7-5b. Clinical Trial Series Module Attributes

Attribute Name	Tag	Type	Attribute Description
Clinical Trial Coordinating Center Name	(0012,0060)	2	The name of the institution that is responsible for coordinating the medical imaging data for the clinical trial or research. See Section C.7.3.2.1.1.
Clinical Trial Series ID	(0012,0071)	3	An identifier of the Series in the context of a clinical trial or research. See Section C.7.3.2.1.2.

Attribute Name	Tag	Type	Attribute Description
Issuer of Clinical Trial Series ID	**(gggg,eee6)**	**3**	**Identifier of the Assigning Authority that issued the Clinical Trial Series ID.**
Clinical Trial Series Description	(0012,0072)	3	A description of the Series in the context of a clinical trial or research. See Section C.7.3.2.1.2.

C.7.3.2.1 Clinical Trial Series Module Attribute Descriptions

C.7.3.2.1.1 Clinical Trial Coordinating Center Name

The Clinical Trial Coordinating Center Name (0012,0060) identifies the institution responsible for coordinating the collection of images and associated data for subjects enrolled in the clinical trial or research.

C.7.3.2.1.2 Clinical Trial Series Identifier and Description

The Clinical Trial Series ID (0012,0071) and Clinical Trial Series Description (0012,0072) Attributes can be used to identify and describe a Series within the context of a clinical trial or research without requiring the replacement of the values in Series Number (0020,0011) and Series Description (0008,103E) Attributes in the ???, whose manufacturer or user provided values may be relevant and important to retain.

For reference unchanged:

10.14 HL7v2 Hierarchic Designator Macro

Table 10-17 specifies the Attributes of the HL7v2 Hierarchic Designator Macro, which identify an entity (system, organization, agency, or department) that has responsibility for managing or assigning a defined set of instance identifiers (such as placer or filler number, Patient identifiers, provider identifiers, etc.). This entity could be a particular health care application such as a registration system that assigns Patient identifiers, a governmental entity such as a licensing authority that assigns professional identifiers or drivers' license numbers, or a facility where such identifiers are assigned.

Note

This definition is identical to HL7 v2.5, Section 2.A.33, with only minor changes for editorial style.

These Attributes are equivalent to the components of the HL7 v2 Hierarchic Designator (HD) and Entity Identifier (EI) data types (see HL7 v2 Chapter 2.A).

If both Local Namespace Entity ID (0040,0031) and Universal Entity ID (0040,0032) are present, they shall refer to the same entity.

Table 10-17. HL7v2 Hierarchic Designator Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Local Namespace Entity ID	(0040,0031)	1C	Identifies an entity within the local namespace or domain. Required if Universal Entity ID (0040,0032) is not present; may be present otherwise.
Universal Entity ID	(0040,0032)	1C	Universal or unique identifier for an entity. Required if Local Namespace Entity ID (0040,0031) is not present; may be present otherwise.

Attribute Name	Tag	Type	Attribute Description
Universal Entity ID Type	(0040,0033)	1C	Standard defining the format of the Universal Entity ID. Required if Universal Entity ID (0040,0032) is present. **Enumerated Values:** **DNS** An Internet dotted name. Either in ASCII or as integers **EUI64** An IEEE Extended Unique Identifier **ISO** An International Standards Organization Object Identifier **URI** Uniform Resource Identifier **UUID** The DCE Universal Unique Identifier **X400** An X.400 MHS identifier **X500** An X.500 directory name

10.15 Issuer of Patient ID Macro

Table 10-18 specifies the Attributes of the Issuer of Patient ID Macro, which identify the source of Patient ID (0010,0020).

These Attributes are equivalent to components of the HL7 v2 Extended Composite ID with Check Digit (CX) data type (see HL7 v2 Chapter 2.A.14), as used in the HL7 v2 PID-3 Patient Identifier List field.

Table 10-18. Issuer of Patient ID Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Issuer of Patient ID	(0010,0021)	3	Identifier of the Assigning Authority (system, organization, agency, or department) that issued the Patient ID. **Note** Equivalent to HL7 v2 CX component 4 subcomponent 1.
Issuer of Patient ID Qualifiers Sequence	(0010,0024)	3	Attributes specifying or qualifying the identity of the issuer of the Patient ID, or scoping the Patient ID. Only a single Item is permitted in this Sequence.
>Universal Entity ID	(0040,0032)	3	Universal or unique identifier for the Patient ID Assigning Authority. The authority identified by this Attribute shall be the same as that of Issuer of Patient ID (0010,0021), if present. **Note** Equivalent to HL7 v2 CX component 4 subcomponent 2 (Universal ID).
>Universal Entity ID Type	(0040,0033)	1C	Standard defining the format of the Universal Entity ID (0040,0032). Required if Universal Entity ID (0040,0032) is present. **Note** Equivalent to HL7 v2 CX component 4 subcomponent 3 (Universal ID Type). See Section 10.14 for Defined Terms.
>Identifier Type Code	(0040,0035)	3	Type of Patient ID. Refer to HL7 v2 Table 0203 for Defined Terms. **Note** Equivalent to HL7 v2 CX component 5 (Identifier Type Code).

Attribute Name	Tag	Type	Attribute Description
>Assigning Facility Sequence	(0040,0036)	3	The place or location identifier where the identifier was first assigned to the Patient. This component is not an inherent part of the identifier but rather part of the history of the identifier. Only a single Item is permitted in this Sequence. **Note** Equivalent to HL7 v2 CX component 6 (Assigning Facility).
>>Include Table 10-17 "HL7v2 Hierarchic Designator Macro Attributes"			
>Assigning Jurisdiction Code Sequence	(0040,0039)	3	The geo-political body that assigned the Patient identifier. Typically a code for a country or a state/province. Only a single Item is permitted in this Sequence. **Note** Equivalent to HL7 v2 CX component 9 (Assigning Jurisdiction).
>>Include ???			*BCID 5001 "Country" for country codes.*
>Assigning Agency or Department Code Sequence	(0040,003A)	3	The agency or department that assigned the Patient identifier. Only a single Item is permitted in this Sequence. **Note** Equivalent to HL7 v2 CX component 10 (Assigning Agency or Department).
>>Include ???			*No Baseline CID is defined.*

C.7.1.1 Patient Module

Table C.7-1. Patient Module Attributes

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010,0010)	2	Patient's full name.
Patient ID	(0010,0020)	2	Primary identifier for the Patient. **Note** In the case of imaging a group of small animals simultaneously, the single value of this identifier corresponds to the identification of the entire group. See also ???.
Include Table 10-18 "Issuer of Patient ID Macro Attributes"			

Attribute Name	Tag	Type	Attribute Description
Type of Patient ID	(0010,0022)	3	The type of identifier in the Patient ID (0010,0020). **Defined Terms:** **TEXT** **RFID** **BARCODE** **Note** 1. The identifier is coded as a string regardless of the type, not as a binary value. 2. When this Attribute has a value of BARCODE, Patient ID (0010,0020) may or may not have the same value as Barcode Value (2200,0005) in the ???, if present.
...			
Other Patient IDs Sequence	(0010,1002)	3	A Sequence of identification numbers or codes used to identify the Patient, which may or may not be human readable, and may or may not have been obtained from an implanted or attached device such as an RFID or barcode. One or more Items are permitted in this Sequence. **Note** This Attribute replaces the use of Other Patient IDs (0010,1000), which did not specify an issuer for each other identifier, and which has been retired.
>Patient ID	(0010,0020)	1	An identifier for the Patient. **Note** In the case of imaging a group of small animals simultaneously, the single value of this identifier corresponds to the identification of the entire group. See also ???.
>Include Table 10-18 "Issuer of Patient ID Macro Attributes"			
>Type of Patient ID	(0010,0022)	1	The type of identifier in the Patient ID (0010,0020) in this Item. **Defined Terms:** **TEXT** **RFID** **BARCODE** **Note** 1. The identifier is coded as a string regardless of the type, not as a binary value. 2. When this Attribute has a value of BARCODE, Patient ID (0010,0020) may or may not have the same value as Barcode Value (2200,0005) in the ???, if present.
Other Patient Names	(0010,1001)	3	Other names used to identify the Patient.
...			

Note

Previously, Other Patient IDs (0010,1000) was included in this table. This Attribute have been retired. See PS3.3-2017a.

Add new data elements to DICOM PS3.6 as follows:

6 Registry of DICOM Data Elements

Table 6-1. Registry of DICOM Data Elements

Tag	Name	Keyword	VR	VM	
(gggg,eee1)	Issuer of Clinical Trial Protocol ID	IssuerOfClinicalTrialProtocolID	LO	1	
(gggg,eee2)	Issuer of Clinical Trial Site ID	IssuerOfClinicalTrialSiteID	LO	1	
(gggg,eee3)	Issuer of Clinical Trial Subject ID	IssuerOfClinicalTrialSubjectID	LO	1	
(gggg,eee4)	Issuer of Clinical Trial Subject Reading ID	IssuerOfClinicalTrialSubjectReadingID	LO	1	
(gggg,eee5)	Other Clinical Trial Protocol IDs Sequence	OtherClinicalTrialProtocolIDs Sequence	SQ	1	

Add new Attributes to DICOM PS3.15 de-identification profile as follows:

E.1.1 De-identifier

Table E.1-1. Application Level Confidentiality Profile Attributes

Attribute Name	Tag	Retd. (from PS3.6)	In Std. Comp. IOD (from PS3.3)	Basic Prof.	Rtn. Safe Priv. Opt.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.	Clean Struct. Cont. Opt.	Clean Graph. Opt.
Issuer of Clinical Trial Protocol ID	(gggg,eee1)	N	Y	X										
Issuer of Clinical Trial Site ID	(gggg,eee2)	N	Y	X										
Issuer of Clinical Trial Subject ID	(gggg,eee3)	N	Y	X										
Issuer of Clinical Trial Subject Reading ID	(gggg,eee4)	N	Y	X										
Other Clinical Trial Protocol IDs Sequence	(gggg,eee5)	N	Y	X										