Status	Assigned
Date of Last Update	2017/01/30
Person Assigned	David Clunie mailto:dclunie@dclunie.com
Submitter Name	TCIA
Submission Date	2017/01/25

Correction Number CP-1693
Log Summary: Add study longitudinal temporal offset from event for clinical trials
Name of Standard PS3.3, PS3.6, PS3.15, PS3.16
Rationale for Correction: For clinical trials, especially for de-identified images from which the actual dates have been remove, it is often important to record not just the sequence of time points but the time interval (usually in days) between events. E.g., to check that imaging has been performed within the correct time window specified in the clinical trial protocol, or to compute rate of change over time. This information may be required in image and SR attributes in the Clinical Trial Study Module, and also may be required in SR templates as local observation context when when multiple measurements in the same instance are from different time points. The word "event" is used rather than "epoch" to describe the point to which offset times are relative, since the latter refers to a period (span) of time rather a single point, and is also overloaded in the context of clinical trials (see https://uts.nlm.nih.gov/metathesaurus.html?cui=C2347803 and https://uts.nlm.nih.gov/metathesaurus.html?cui=C1948053).
Correction Wording:

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

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 ???.
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 ???.
Longitudinal Temporal Offset from Event	**(0012,eee1)**	**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.**
Longitudinal Temporal Event Type	**(0012,eee2)**	**1C**	**The type of event to which Longitudinal Temporal Offset from Event (0012,eee1) 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,eee1) 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 ???.
...	...	...	...

*Amend DICOM PS3.6 as follows (changes to existing text are bold and **underlined** for additions and ~~**struckthrough**~~ for removals):*

6 Registry of DICOM Data Elements

Table 6-1. Registry of DICOM Data Elements

Tag	Name	Keyword	VR	VM	
(0012,0051)	Clinical Trial Time Point Description	ClinicalTrialTimePointDescription	ST	1	
(0012,eee1)	**Longitudinal Temporal Offset from Event**	**LongitudinalTemporalOffsetFromEvent**	**FD**	**1**	
(0012,eee2)	**Longitudinal Temporal Event Type**	**LongitudinalTemporalEventType**	**CS**	**1**	

*Amend DICOM PS3.15 as follows (changes to existing text are bold and **underlined** for additions and ~~**struckthrough**~~ for removals):*

E.3.6 Retain Longitudinal Temporal Information Options

Dates and times are recognized as having a potential for leakage of identity because they constrain the number of possible individuals that could be the imaging subject, though only if there is access to other information about the individuals concerned to match it against.

However, there are applications that require dates and times to be present to able to fulfill the objective. This is particularly true in therapeutic clinical trials in which the objective is to measure change in an outcome measure over time. Further, it is often necessary to correlate information from images with information from other sources, such as clinical and laboratory data, and dates and times need to be consistent.

Two options are specified to address these requirements:

- Retain Longitudinal Temporal Information With Full Dates Option
- Retain Longitudinal Temporal Information With Modified Dates Option

When the Retain Longitudinal Temporal Information With Full Dates Option is specified in addition to an Application Level Confidentiality Profile, any dates and times present in the Attributes shall be retained, as described in ???. The Attribute Longitudinal Temporal Information Modified (0028,0303) shall be added to the Dataset with a value of "UNMODIFIED".

When the Retain Longitudinal Temporal Information With Modified Dates Option is specified in addition to an Application Level Confidentiality Profile, any dates and times present in the Attributes listed in ??? shall be modified. The modification of the dates and times shall be performed in a manner that:

- aggregates or transforms dates so as to reduce the possibility of matching for re-identification
- preserves the gross longitudinal temporal relationships between images obtained on different dates to the extent necessary for the application
- preserves the fine temporal relationships between images and real-world events to the extent necessary for analysis of the images for the application

The Attribute Longitudinal Temporal Information Modified (0028,0303) shall be added to the Dataset with a value of "MODIFIED".

Note

1. Aggregation of dates may be performed by various means such as setting all dates to the first day of the month, all months to the first month of the year, etc., depending on the precision required for the application.
2. It is possible to modify all dates and times to dummy values by shifting them relative to an arbitrary **~~epoch~~event**, and hence retain the precise longitudinal temporal relationships amongst a set of studies, when either de-identification of the entire set is performed at the same time, or some sort of mapping or database is kept to repeat this process on separate occasions. **It may also be desirable to record the type of event and the temporal offset from that event, and Attributes are provided for that purpose; see Longitudinal Temporal Offset from Event (0012,eee1) and Longitudinal Temporal Event Type (0012,eee2) in the PS3.3 Clinical Trial Study Module.**
3. Transformation of dates and times should be considered together, in order to address studies that span midnight.
4. Any transformation of times should be performed in such a manner as to not disrupt computations needed for analysis, such as comparison of start of injection time to the acquisition time for PET SUV, or extraction of time-intensity values from dynamic contrast enhanced studies.

The manner of date modification shall be described in the Conformance Statement.

*Amend DICOM PS3.16 as follows (changes to existing text are bold and **underlined** for additions and **~~struckthrough~~** for removals):*

TID 1502 Time Point Context

Table TID 1502. Time Point Context

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		HAS OBS CONTEXT	TEXT	EV (126070, DCM, "Subject Time Point Identifier")	1	U		

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
2		HAS OBS CONTEXT	TEXT	EV (126071, DCM, "Protocol Time Point Identifier")	1	U		
3		HAS OBS CONTEXT	TEXT	EV (C2348792, UMLS, "Time Point")	1	M		
4		HAS OBS CONTEXT	CODE	EV (126072, DCM, "Time Point Type")	1-n	U		B???
5		HAS OBS CONTEXT	NUM	EV (126073, DCM, "Time Point Order")	1	U		UNITS = EV (1, UCUM, "no units")
6		**HAS OBS CONTEXT**	**NUM**	**EV (ddd001, DCM, "Longitudinal Temporal Offset from Event")**	**1**	**U**		**UNITS = DT (d, UCUM, "days")**
7	**>**	**HAS CONCEPT MOD**	**CODE**	**EV (ddd002, DCM, "Longitudinal Temporal Event Type")**	**1**	**M**		**DCID cccc1 "Longitudinal Temporal Event Types"**

Content Item Descriptions

Row 1	Usually the same value as the Clinical Trial Time Point ID (0012,0050) attribute in the Clinical Trial Study Module, though not confined to clinical trial use. May or may not be human readable, and not required to be a DICOM UID.
Row 2	All of the subjects within a treatment protocol that are examined at a particular scheduled time point (e.g., "baseline", "pre-treatment", "first post-treatment") will have the same Protocol Time Point Identifier, but different Subject Time Point Identifiers. However, in different protocols, the Protocol Time Point Identifiers for the same conceptual "time point" will be different. E.g., the "baseline" time point will have different Protocol Time Point Identifiers in different protocols. May or may not be human readable, and not required to be a DICOM UID.
Row 3	Typically a short pre-defined label that has the same scope as Protocol Time Point Identifier (i.e., same conceptual time point within a treatment protocol) but is human-readable and understandable, e.g., "BASELINE" or "TP0", "TP1", etc. Usually the same value as Clinical Trial Time Point Description (0012,0051) attribute in the Clinical Trial Study Module, though not confined to clinical trial use. The Concept Name is selected as (C2348792, UMLS, "Time Point") (which is (C68568, NCIt, "Time Point"), defined as "a specific point in the time continuum, including those established relative to an event") in order to be compatible with external terminologies.
Row 4	More than one type is permitted, e.g., a time point may be "posttreatment" as well as "unscheduled" or "nadir", etc.
Row 5	The order is expected to be monotonically increasing within a particular scope of usage, but is not required to start at 0 or 1, nor required to increase in increments of 1 or even the same increment (e.g., to allow for retrospective insertion of unscheduled time points). In clinical usage, the Time Point Order would be expected to be temporally increasing, but in a clinical trial may be a randomized reading order rather than a temporal order.
Rows 6, 7	**Longitudinal temporal information may be inherited from Longitudinal Temporal Offset from Event (0012,eee1) and Longitudinal Temporal Event Type (0012,eee2) in the PS3.3 Clinical Trial Study Module, or may be specified or overridden within this template (e.g., if different measurements in the same SR Instance were measured on different time points).**

CID cccc1 Longitudinal Temporal Event Types

Type: **Extensible**
Version: **yyyymmdd**

Table CID cccc1. Longitudinal Temporal Event Types

Coding Scheme Designator	Code Value	Code Meaning	SNOMED-CT Concept ID	UMLS Concept Unique ID
NCIt	**C37948**	**Enrollment**		**C1516879**

Coding Scheme Designator	Code Value	Code Meaning	SNOMED-CT Concept ID	UMLS Concept Unique ID
DCM	121079	Baseline		

D DICOM Controlled Terminology Definitions (Normative)

Table D-1. DICOM Controlled Terminology Definitions

Code Value	Code Meaning	Definition	Notes
121079	Baseline	Initial images used to establish a beginning condition that is used for comparison over time to look for changes. [Paraphrases NCI-PT (C1442488, UMLS, "Baseline"), which is defined as "An initial measurement that is taken at an early time point to represent a beginning condition, and is used for comparison over time to look for changes. For example, the size of a tumor will be measured before treatment (baseline) and then afterwards to see if the treatment had an effect. A starting point to which things may be compared."]	
ddd001	Longitudinal Temporal Offset from Event	An offset in time from a particular event of significance. In the context of a clinical trial, this is often the time since enrollment, or the baseline imaging study.	
ddd002	Longitudinal Temporal Event Type	The type of event to which a temporal offset is relative.	