

### DICOM Correction Item

Correction Number	CP-507	
Log Summary:	Modify MWL / GP-WL for clinical trial participation and anonymization	
Type of Modification	Name of Standard	
Addition	PS 3.3, 3.6 2004	
Rationale for Correction:		
<p>Supplement 70 added attributes for Clinical Trial identification, but defined no means to provide those attributes to a modality or workstation.</p> <p>This CP adds Clinical Trial identification attributes to the Patient Medical Module, and hence to the Modality and General Purpose Worklists. The identifiers are provided as a list (sequence of items), since a patient may be enrolled in several trials. This list allows a user at the modality or workstation to identify an appropriate Clinical Trial procedure to be used for acquisition or processing of the study, as well as providing the subject identifiers necessary for inclusion in the acquired data.</p>		
Sections of documents affected		
PS 3.3 Annex C.2.4		
PS 3.6 Section 6		
Correction Wording:		

**Modify Part 3 Table C.2-4 Patient Medical Module (used in Modality and General Purpose Worklists, and invoked in Part 4 as "All other attributes of Patient Medical Module"):**

#### C.2.4 Patient Medical Module

Table C.2-4 defines the Attributes relevant to a patient's medical state or history.

**Table C.2-4  
 PATIENT MEDICAL MODULE ATTRIBUTES**

Attribute Name	Tag	Attribute Description
...		
Patient State	(0038,0500)	Description of patient state (comatose, disoriented, vision impaired, etc.)
<b><u>Patient Clinical Trial Participation Sequence</u></b>	<b><u>(0038,0502)</u></b>	<b><u>Sequence of identifiers for clinical trials in which the patient participates.</u></b> <b><u>Zero or more Items may be included in this sequence.</u></b>
<b><u>&gt;Clinical Trial Sponsor Name</u></b>	<b><u>(0012,0010)</u></b>	<b><u>The name of the clinical trial sponsor, responsible for conducting the clinical trial and for defining the Clinical Trial Protocol.</u></b>
<b><u>&gt;Clinical Trial Protocol ID</u></b>	<b><u>(0012,0020)</u></b>	<b><u>Identifier for the noted protocol, used by the Clinical Trial Sponsor to uniquely identify the investigational protocol.</u></b>
<b><u>&gt;Clinical Trial Protocol Name</u></b>	<b><u>(0012,0021)</u></b>	<b><u>The name or title of the clinical trial protocol.</u></b>

<b>&gt;Clinical Trial Site ID</b>	<b>(0012,0030)</b>	<b>The identifier, issued by the Clinical Trial Sponsor, of the site responsible for submitting clinical trial data.</b>
<b>&gt;Clinical Trial Site Name</b>	<b>(0012,0031)</b>	<b>Name of the site responsible for submitting clinical trial data.</b>
<b>&gt;Clinical Trial Subject ID</b>	<b>(0012,0040)</b>	<b>The assigned identifier for the patient as a clinical trial subject.</b>
<b>&gt;Clinical Trial Subject Reading ID</b>	<b>(0012,0042)</b>	<b>Identifies the patient as a clinical trial subject for blinded evaluations.</b>

**Note:** The Patient Clinical Trial Participation Sequence (0038,0502) identifies potentially multiple trials in which the patient is enrolled. Application behavior in the presence of multiple items is outside the scope of the standard.

**Add the following to Part 6 Section 6 Registry of DICOM Data Elements:**

**(0038,0502)    Patient Clinical Trial Participation Sequence                      SQ                      1**