Digital Imaging and Communications in Medicine (DICOM)

Supplement 70: Clinical Trial Identification

DICOM Standards Committee, Working Group 18 Clinical Trials

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Foreword

This supplement to the DICOM Standard defines a set of Clinical Trial Identification Modules consisting of a Clinical Trial Subject module, a Clinical Trial Study module, and a Clinical Trial Series module, which provide an alternate means of identifying DICOM information objects used in clinical trials.

Scope and Field of Application

The Clinical Trial Identification modules are a means for identifying images and related data acquired for subjects involved in clinical trials. They are intended to be useful for data submission and re-transmission in both national and international regulatory trials and multi-institutional cooperative-group investigations.

The Clinical Trial Identification modules provide a mechanism to identify clinical trial images and data by including descriptive information that is unique within the context of a given clinical trial. The additional descriptive parameters outlined in these modules include the clinical trial sponsor, clinical trial protocol, clinical trial site, clinical trial subject identification number, clinical trial subject reading number, clinical trial time point, and clinical trial coordinating center.

The Clinical Trial Identification modules alone do not remove personal identification or otherwise specify which attributes of DICOM information objects should be removed or replaced to assure patient confidentiality. This decision should be made after considering the regulations of each country and/or its sub-regions, and in accordance with PS 3.15 (Security Profiles). Instead, the module provides an

alternative means for identifying DICOM information objects when personal identification is absent or hidden.

This Supplement includes a number of Addenda to existing Parts of DICOM:

1. Part 3 Addenda (Extension to Annex A and C)
2. Part 6 Addenda (Extension to Section 6)

In PS 3.3 Section 7 add the following section

7.6 EXTENSION OF THE DICOM MODEL OF THE REAL WORLD FOR CLINICAL TRIALS

The DICOM Model of the Real World is extended for Clinical Trials with the addition of several objects whose relationships to each other and existing DICOM Real World objects are shown in Figure 7.6-1.

Attributes of the Clinical Trial Sponsor, Clinical Trial Protocol, Clinical Trial Subject, and Clinical Trial Site objects are represented in the Clinical Trial Subject Module within the Patient IOD. Attributes of the Clinical Trial Time Point object are represented in the Clinical Trial Study Module within the Study IOD. The Clinical Trial Coordinating Center attribute is represented in the Clinical Trial Series Module within Image IODs.

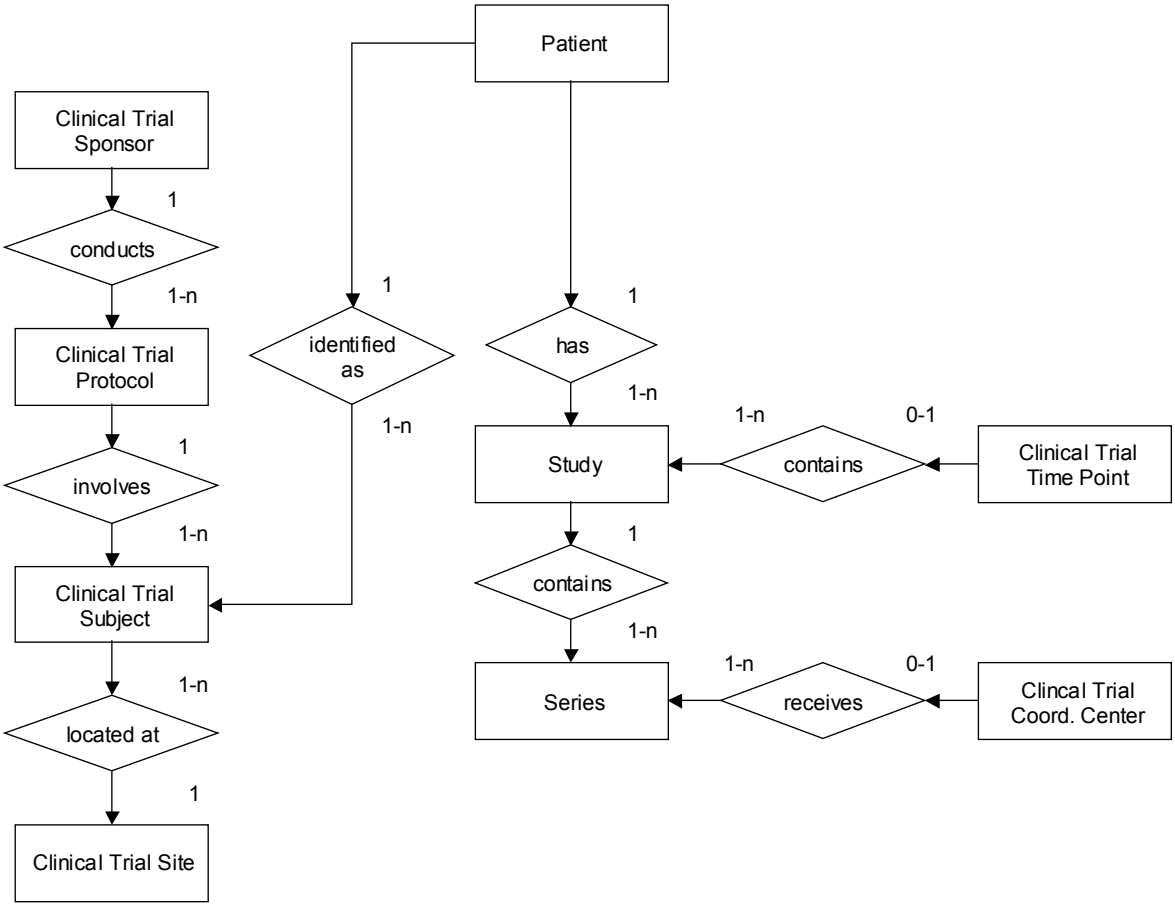

Figure 7.6-1 – DICOM MODEL OF THE REAL WORLD – CLINICAL TRIALS

7.6.1 Clinical Trial Information Entities

For the purpose of Clinical Trial Information, an extension of the DICOM Model of the Real World is made, as depicted in Figure 7.6-1.

7.6.1.1 Clinical Trial Sponsor

A Clinical Trial Sponsor identifies the agency, group, or institution responsible for conducting the clinical trial and for assigning a Protocol Identifier.

7.6.1.2 Clinical Trial Protocol

A Clinical Trial Protocol identifies the investigational Protocol in which the Subject has been enrolled. The Protocol has a Protocol Identifier and Protocol Name.

7.6.1.3 Clinical Trial Subject

A Clinical Trial Subject identifies the Patient who is enrolled as a Subject in the investigational Protocol.

7.6.1.4 Clinical Trial Site

A Clinical Trial Site identifies the location or institution at which the Subject is treated or evaluated and which is responsible for submitting clinical trial data. Images and/or clinical trial data may be collected for a given Subject at alternate institutions, e.g. follow-up scans at a satellite imaging center, but the Clinical Trial Site represents the primary location for Patient management and data submission in the context of a clinical trial.

7.6.1.5 Clinical Trial Time Point

The Clinical Trial Time Point identifies an imaging Study within the context of an investigational protocol. A Time Point defines a set of studies that are grouped together as a clinical time point or submission in a clinical trial.

7.6.1.6 Clinical Trial Coordinating Center

The Clinical Trial Coordinating Center identifies the institution responsible for coordinating the collection, management, processing, and/or analysis of images and associated data for Subjects enrolled in a clinical trial. Within a given Clinical Trial Protocol, there may be multiple Clinical Trial Coordinating Centers, each handling different aspects of the clinical data submitted by the Clinical Trial Sites.

Add the following informative annex to PS 3.3

Annex X. Clinical Trial Identification Workflow Examples (Informative)

The Clinical Trial Identification modules are optional. As such, there are several points in the workflow of clinical trial data at which the Clinical Trial Identification attributes may be added to the data. At the Clinical Trial Site, the attributes may be added at the scanner, a PACS system, a site workstation, or a workstation provided to the site by a Clinical Trial Coordinating Center. If not added at the site, the Clinical Trial Identification attributes may be added to the data after receipt by the Clinical Trial Coordinating Center. The addition of clinical trial attributes does not itself require changes to the SOP Instance UID. However, the clinical trial protocol or the process of de-identification may require such a change.

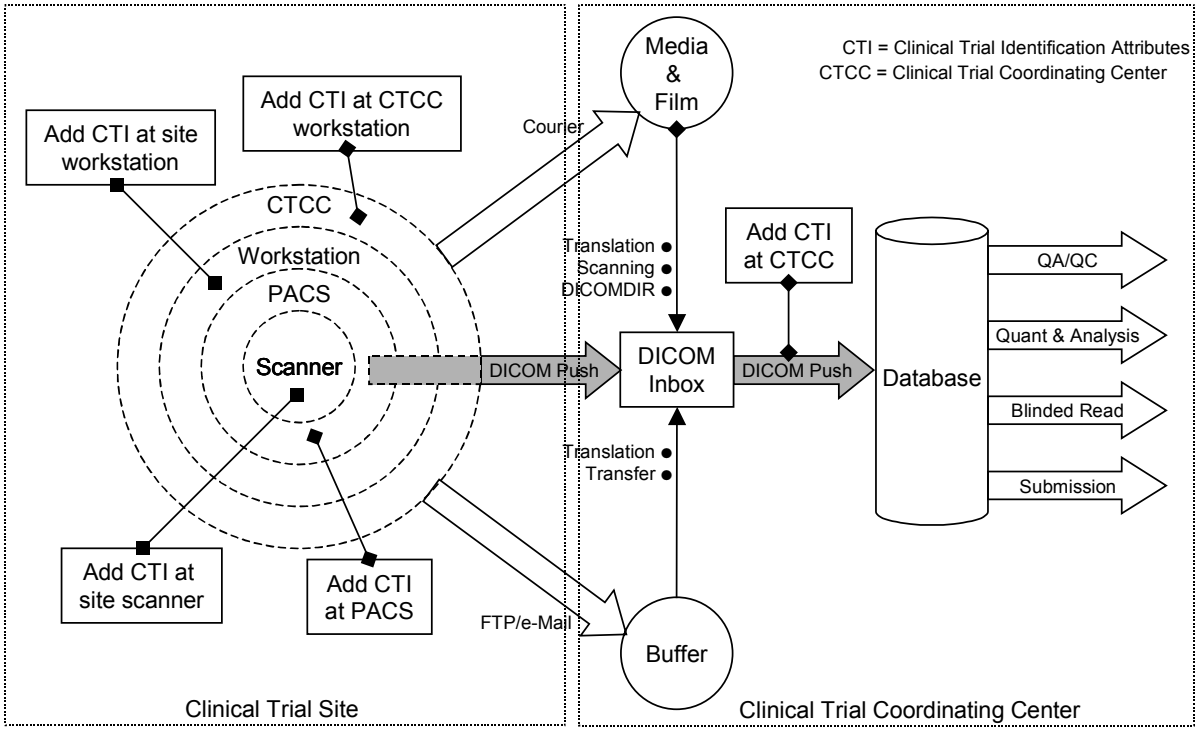

Figure X-1 – Workflow Diagram for Clinical Trials

X.1 Example Use-Case

Images are obtained for the purpose of comparing patients treated with placebo or the drug under test, then evaluated in a blinded manner by a team of radiologists at the Clinical Trial Coordinating Center

(CTCC). The images are obtained at the clinical sites, collected by the CTCC, at which time their identifying attributes are removed and the Clinical Trial Identification (CTI) module is added. The de-identified images with the CTI information are then presented to the radiologists who make quantitative and/or qualitative assessments. The assessments, and in some cases the images, are returned to the sponsor for analysis, and later are contributed to the submission to the regulating authority.

Part 3 Addendum

Add in Annex A - Clinical Trial Subject Module, Clinical Trial Study Module, and Clinical Trial Series Module (User-optional for all composite IODs).

After PS 3.3 Section C.7.1.2 add the following:

C.7.1.3 Clinical Trial Subject Module

Table C.7-X contains attributes that identify a Patient as a clinical trial Subject.

Table C.7-X—Clinical Trial Subject Module

Attribute Name	Tag	Type	Attribute Description
Clinical Trial Sponsor Name	(0012,0010)	1	The name of the clinical trial sponsor. See C.7.1.3.1.1.
Clinical Trial Protocol ID	(0012,0020)	1	~~I~~dentifier for the noted protocol. See C.7.1.3.1.2.
Clinical Trial Protocol Name	(0012,0021)	2	The name of the clinical trial protocol. See C.7.1.3.1.3.
Clinical Trial Site ID	(0012,0030)	2	The identifier of the site responsible for submitting clinical trial data. See C.7.1.3.1.4.
Clinical Trial Site Name	(0012,0031)	2	Name of the site responsible for submitting clinical trial data. See C.7.1.3.1.5
Clinical Trial Subject ID	(0012,0040)	1C	The assigned identifier for the clinical trial subject. See C.7.1.3.1.6. Shall be present if Clinical Trial Subject Reading ID (0012,0042) is absent. May be present otherwise.
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 C.7.1.3.1.7.

C.7.1.3.1 Clinical Trial Subject Attribute Descriptions

Identification of subjects in clinical trials 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 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.

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 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 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 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).

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.

After Section C.7.2.2 add the following:

C.7.2.3 Clinical Trial Study Module

Table C.7-Y contains attributes that identify a Study in the context of a clinical trial.

Table C.7-Y—Clinical Trial Study Module

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. See C.7.2.3.1.1.
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. See C.7.2.3.1.1.

C.7.2.3.1 Clinical Trial Study 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. 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.

After PS 3.3 Section C.7.3.1 add the following:

C.7.3.2 Clinical Trial Series Module

Table C.7-Z contains attributes that identify a Series in the context of a clinical trial.

Table C.7-Z—Clinical Trial Series Module

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. See C.7.3.2.1.1.

C.7.3.2.1 Clinical Trial Series 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.

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Part 6 Addendum

Add the following Data Elements to PS 3.6 Section 6

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Tag	Name	VR	VM
(0012,0010)	Clinical Trial Sponsor Name	LO	**1**
(0012,0020)	Clinical Trial Protocol ID	LO	**1**
(0012,0021)	Clinical Trial Protocol Name	LO	**1**
(0012,0030)	Clinical Trial Site ID	LO	**1**
(0012,0031)	Clinical Trial Site Name	LO	**1**
(0012,0040)	Clinical Trial Subject ID	LO	**1**
(0012,0042)	Clinical Trial Subject Reading ID	LO	**1**
(0012,0050)	Clinical Trial Time Point ID	LO	**1**
(0012,0051)	Clinical Trial Time Point Description	ST	**1**
(0012,0060)	Clinical Trial Coordinating Center Name	LO	**1**

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