ODM

CDISC ODM Model DTD Version Version 1.0

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Change History:

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28-Aug-2000 edited by David Fram:

Renamed SigningUnit to be Form.

Removed attribute PTKey from ItemData and PatientData.

Modified StudyEventKey, FormKey, ItemGroupKey, ItemKey to have EMPTY content.

Added "datetime", "time" to list of item data types; removed "abstract".

Modified Country element to have an attribute called "Name"; made its content be EMPTY.

Inserted ISO-3166 2-letter values as legal values for Name attribute of Country. Note slight problem: BY seems to be the 2-letter code for both BELARUS and BYELORUSSIAN SSR.

Inserted ISO-639 2-letter values as legal values for Name attribute of Language.

Added "wrapper tag" to distinguish between "flat" and "hierarchical" organizations for clinical data. Now, a Study has either HierData OR FlatData BUT NOT BOTH. Changed naming of PatientData, StudyEventData, FormData, etc. to be HierPatientData, HierStudyEventData, HierFormData, etc. Added parallel set of flat elements: FlatPatientData, FlatStudyEventData, FlatFormData, etc. Higher-level keys are required within flat elements, and are not permitted within hierarchical elements.

Renamed Gender attribute to be Sex. Enumerated permitted values for Sex as (M | F).

Corrected definition of Signature so that it contains one and only one UserRef and contains one and only one LocationRef.

Made naming more consistent for DST (daylight savings time) attributes of TimeZone. Renamed DSTStartHr to be DSTStartHour.

Modified Picture element to be consistent with new convention for referencing external files.

Modified ArchiveLayout element to have EMPTY content (and to be consistent with new convention for referencing external files).

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Note on commenting convention: In order to support the generation of a hyper-linked pretty-printed version of the DTD, the following comment conventions should be observed:

This comment (which appears on the "home page") should begin with the text "-home-:" followed by a newline.

Before each ELEMENT definition, there should be a comment that begins with the text "element-name:" followed by dashes

and a newline.

Before each ATTLIST definition, there should be a comment that begins with the text "element-name*:" followed by a newline.

Note on use of attributes: The DTD has been updated (June 2000) to use attributes extensively for short, single-valued parameter values. Thus, for example, the unique identifier of an element (such as a StudyEvent, Form, or ItemGroup) is provided through an XML ID attribute. Similarly, "foreign-key" style references to other elements are provided via attributes of type XML IDREF. Also, many scalar-valued "leaf" elements are provided via XML CDATA attributes.

Note: Certain identifier conventions have been followed regarding Names, IDs and ID-references. Attributes called "ID" (of type XML ID) and called "Name" (of type XML CDATA) are standardly used to identify an element; these attributes are usually declared as REQUIRED. The ID provides a unique handle for cross-referencing from other elements.

If element yyy needs to reference one or more elements xxx, then yyy will contain as part of its content an element with the name xxxRef and that element will, in turn, have an attribute with the name xxxID. The term "reference identifier" is used to denote the element xxxRef and its associated attribute xxxID.

Thus, for example, a StudyEvent contains 0 or more FormRef's, and a FormRef is defined to have an attribute called FormID.

Note: Every attribute of the form xxxID should be an attribute of an element with the name xxxRef. So, references to other elements always go through a contained xxxRef element.

Top Elements
All Elements
Tree

Document generated by `dtd2html` 1.5.1.

ODM

Top elements in ODM

- **[Study](#)**

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Study

Includes all aspects of a clinical study (metadata, administrative data, and clinical data).

Content:

(GlobalVariables,BasicDefinitions,MetaDataVersion+,AdminData, (HierData|FlatData))

Attributes:

No ATTRIBUTES

Containing Elements:

None

Top Elements
All Elements
Tree

ODM

GlobalVariables

GlobalVariables includes general summary information about the study that is described by the XML document.

Content:

(StudyName,StudyDescription,ProtocolName)

Attributes:

No ATTRIBUTES

Containing Elements:

- **Study**

Top Elements
All Elements
Tree

ODM

StudyName

StudyName contains a short name for the study.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **GlobalVariables**

Top Elements
All Elements
Tree

ODM

BasicDefinitions

BasicDefinitions contains definitions of information that does not typically vary between studies.

Content:

([Language](#)*,[Locale](#)*,[TimeZone](#)*,[MeasurementUnit](#)*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **[Study](#)**

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Language

Language contains the name of a language used in the study. (This should use the ISO 2-letter language codes.)

Content:

```
EMPTY
```

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element (ISO 639 2-letter language codes)

ID	ID	*#REQUIRED*
Name	(aa | ab | af | am | ar | as | ay | az | ba | be | bg | bh | bi | bn | bo | br | ca | co | cs | cy | da | de | dz | el | en | eo | es | et | eu | fa | fi | fj | fo | fr | fy | ga | gd | gl | gn | gu | ha | he | hi | hr | hu | hy | ia | id | ie | ik | is | it | iu | ja | jw | ka | kk | kl | km | kn | ko | ks | ku | ky | la | ln | lo | lt | lv | mg | mi | mk | ml | mn | mo | mr | ms | mt | my | na | ne | nl | no | oc | om | or | pa | pl | ps | pt | qu | rm | rn | ro | ru | rw | sa | sd | sg | sh | si | sk | sl | sm | sn | so | sq | sr | ss | st | su | sv | sw | ta | te | tg | th | ti | tk | tl | tn | to | tr | ts | tt | tw | ug | uk | ur | uz | vi | vo | wo | xh | yi | yo | za | zh | zu)	*#REQUIRED*

Containing Elements:

- **BasicDefinitions**

Top Elements
All Elements
Tree

ODM

All elements in ODM

- **Address**
- **AdminData**
- **ArchiveLayout**
- **BasicDefinitions**
- **Certificate**
- **CheckValue**
- **City**
- **CodeList**
- **CodeListItem**
- **CodeListRef**
- **Comment**
- **CommentText**
- **Country**
- **CryptoBindingManifest**
- **DateTimeStamp**
- **Decode**
- **DisplayName**
- **Email**
- **ErrorMessage**
- **Fax**
- **FirstName**
- **FlatData**
- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **FlatPatientData**
- **FlatStudyEventData**
- **Form**
- **FormKey**
- **FormRef**
- **FullName**
- **GlobalVariables**
- **HierData**
- **HierFormData**
- **HierItemData**
- **HierItemGroupData**

- **HierPatientData**
- **HierStudyEventData**
- **Item**
- **ItemGroup**
- **ItemGroupKey**
- **ItemGroupRef**
- **ItemKey**
- **ItemRef**
- **Language**
- **LastName**
- **LegalReason**
- **Locale**
- **Location**
- **LocationRef**
- **LoginName**
- **Meaning**
- **MeasurementUnit**
- **MeasurementUnitRef**
- **MetaDataVersion**
- **MetaDataVersionRef**
- **Organization**
- **OtherText**
- **Pager**
- **PatientKey**
- **Phone**
- **Picture**
- **PostalCode**
- **Presentation**
- **ProtocolName**
- **Question**
- **RangeCheck**
- **ReasonForChange**
- **Signature**
- **SignatureDef**
- **SignatureDefRef**
- **StateProv**
- **StreetName**
- **Study**

- **StudyDescription**

- **StudyEvent**

- **StudyEventKey**

- **StudyEventRef**

- **StudyName**

- **StudyProtocol**

- **Symbol**

- **TimeZone**

- **TranslatedText**

- **User**

- **UserRef**

- **Value**

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Address

Mailing address of a user of a data collection system.

Content:

(StreetName*,City?,StateProv?,Country?,PostalCode?,OtherText?)

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

StreetName

Street name component of system user's address.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

AdminData

Administrative information about users, locations, and signature definitions.

Content:

([User](#)*,[Location](#)*,[SignatureDef](#)*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **[Study](#)**

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User

Information about a specific user of a clinical data collection system. May be an investigator, a CRA or a data management staff person.

Content:

(LoginName?,DisplayName?,FullName?,FirstName,LastName,
Organization?,Address*,Email*,Picture?,Pager?,Fax*,Phone*,
LocationRef*,Certificate*)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

| **ID** | ID | *#REQUIRED* |
| **Name** | CDATA | *#REQUIRED* |

Containing Elements:

- **AdminData**

Top Elements
All Elements
Tree

ODM

LoginName

System login name of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

ODM:
Top element tree(s)

Study

```
Study
|_(GlobalVariables,
|    |_(StudyName,
|    |    |_(#PCDATA)
|    |
|    |__StudyDescription,
|    |    |_(#PCDATA)
|    |
|    |__ProtocolName)
|         |_(#PCDATA)
|
|
|__BasicDefinitions,
|    |_(Language*,
|    |    |_EMPTY
|    |
|    |__Locale*,
|    |    |_EMPTY
|    |
|    |__TimeZone*,
|    |    |_EMPTY
|    |
|    |__MeasurementUnit*)
|         |_(Symbol)
|              |_(TranslatedText*)
|                   |_(#PCDATA)
|
|
|
|
|__MetaDataVersion+,
|    |_(StudyProtocol,
|    |    |_(StudyEventRef*)
|    |         |_EMPTY
|    |
|    |
|    |__StudyEvent+,
|    |    |_(FormRef+)
|    |         |_EMPTY
|    |
|    |
|    |__Form+,
|    |    |_(ItemGroupRef+,
|    |    |    |_EMPTY
|    |    |
```

```
│    │    │__ArchiveLayout*)
│    │         │_EMPTY
│    │
│    │
│    │__ItemGroup+,
│    │    │_(ItemRef+)
│    │         │_EMPTY
│    │
│    │
│    │__Item+,
│    │    │_(Question?,
│    │    │    │_(TranslatedText*) ...
│    │    │
│    │    │__CodeListRef?,
│    │    │    │_EMPTY
│    │    │
│    │    │__RangeCheck*,
│    │    │    │_(CheckValue*,
│    │    │    │    │_(#PCDATA)
│    │    │    │
│    │    │    │__ErrorMessage?)
│    │    │         │_(TranslatedText*) ...
│    │    │
│    │    │__MeasurementUnitRef*)
│    │         │_EMPTY
│    │
│    │
│    │__CodeList*,
│    │    │_(CodeListItem*)
│    │         │_(Decode)
│    │              │_(TranslatedText+) ...
│    │
│    │
│    │
│    │__Presentation*)
│         │_(#PCDATA)
│
│
│__AdminData,
│    │_(User*,
│    │    │_(LoginName?,
│    │    │    │_(#PCDATA)
│    │    │
│    │    │__DisplayName?,
│    │    │    │_(#PCDATA)
│    │    │
│    │    │__FullName?,
│    │    │    │_(#PCDATA)
│    │    │
│    │    │__FirstName,
│    │    │    │_(#PCDATA)
│    │    │
│    │    │__LastName,
│    │    │    │_(#PCDATA)
│    │    │
│    │    │__Organization?,
```

```
|   |   |   |_(#PCDATA)
|   |   |
|   |   |___Address*,
|   |   |   |_(StreetName*,
|   |   |   |   |_(#PCDATA)
|   |   |   |
|   |   |   |___City?,
|   |   |   |   |_(#PCDATA)
|   |   |   |
|   |   |   |___StateProv?,
|   |   |   |   |_(#PCDATA)
|   |   |   |
|   |   |   |___Country?,
|   |   |   |   |_EMPTY
|   |   |   |
|   |   |   |___PostalCode?,
|   |   |   |   |_(#PCDATA)
|   |   |   |
|   |   |   |___OtherText?)
|   |   |       |_(#PCDATA)
|   |   |
|   |   |___Email*,
|   |   |   |_(#PCDATA)
|   |   |
|   |   |___Picture?,
|   |   |   |_EMPTY
|   |   |
|   |   |___Pager?,
|   |   |   |_(#PCDATA)
|   |   |
|   |   |___Fax*,
|   |   |   |_(#PCDATA)
|   |   |
|   |   |___Phone*,
|   |   |   |_(#PCDATA)
|   |   |
|   |   |___LocationRef*,
|   |   |   |_EMPTY
|   |   |
|   |   |___Certificate*)
|   |       |_(#PCDATA)
|   |
|   |___Location*,
|   |   |_(MetaDataVersionRef)
|   |       |_EMPTY
|   |
|   |___SignatureDef*)
|       |_(Meaning,
|       |   |_(#PCDATA)
|       |
|       |___LegalReason)
|           |_(#PCDATA)
|
|
|
```

```
|__(HierData |
|     |_(HierPatientData*)
|         |_(PatientKey,
|         |    |_(#PCDATA)
|         |
|         |__Comment?,
|         |    |_(CommentText)
|         |         |_(#PCDATA)
|         |
|         |
|         |__HierStudyEventData*,
|         |    |_(StudyEventKey, ...
|         |    |__Comment?, ...
|         |    |__HierFormData*,
|         |    |    |_(FormKey, ...
|         |    |    |__Comment?, ...
|         |    |    |__HierItemGroupData*,
|         |    |    |    |_(ItemGroupKey, ...
|         |    |    |    |__Comment?, ...
|         |    |    |    |__HierItemData*,
|         |    |    |    |    |_(ItemKey, ...
|         |    |    |    |    |__Value?, ...
|         |    |    |    |    |__MeasurementUnitRef?, ...
|         |    |    |    |    |__Comment?, ...
|         |    |    |    |    |__Signature?, ...
|         |    |    |    |    |__ReasonForChange?) ...
|         |    |    |    |
|         |    |    |    |__Signature?, ...
|         |    |    |    |__ReasonForChange?) ...
|         |    |    |
|         |    |    |__Signature, ...
|         |    |    |__ReasonForChange?) ...
|         |    |
|         |    |__Signature?, ...
|         |    |__ReasonForChange?) ...
|         |
|         |__Signature?,
|         |    |_(CryptoBindingManifest?,
|         |    |    |_(#PCDATA)
|         |    |
|         |    |__UserRef,
|         |    |    |_EMPTY
|         |    |
|         |    |__LocationRef, ...
|         |    |__SignatureDefRef,
|         |    |    |_EMPTY
|         |    |
|         |    |__DateTimeStamp)
|         |         |_(#PCDATA)
|         |
|         |
|         |__ReasonForChange?)
|              |_(#PCDATA)
|
|
|
```

```
        |___FlatData))
            |_(FlatPatientData*,
            |    |_(PatientKey, ...
            |    |__Comment?, ...
            |    |__Signature?, ...
            |    |__ReasonForChange?) ...
            |
            |__FlatStudyEventData*,
            |    |_(PatientKey, ...
            |    |__StudyEventKey,
            |    |    |_EMPTY
            |    |
            |    |__Comment?, ...
            |    |__Signature?, ...
            |    |__ReasonForChange?) ...
            |
            |__FlatFormData*,
            |    |_(PatientKey, ...
            |    |__StudyEventKey, ...
            |    |__FormKey,
            |    |    |_EMPTY
            |    |
            |    |__Comment?, ...
            |    |__Signature, ...
            |    |__ReasonForChange?) ...
            |
            |__FlatItemGroupData*,
            |    |_(PatientKey, ...
            |    |__StudyEventKey, ...
            |    |__FormKey, ...
            |    |__ItemGroupKey,
            |    |    |_EMPTY
            |    |
            |    |__Comment?, ...
            |    |__Signature?, ...
            |    |__ReasonForChange?) ...
            |
            |__FlatItemData*)
                |_(PatientKey, ...
                |__StudyEventKey, ...
                |__FormKey, ...
                |__ItemGroupKey, ...
                |__ItemKey,
                |    |_EMPTY
                |
                |__Value?,
                |    |_(#PCDATA)
                |
                |__MeasurementUnitRef?, ...
                |__Comment?, ...
                |__Signature?, ...
                |__ReasonForChange?) ...
```

Top Elements
All Elements
Tree

ODM

StudyDescription

StudyDescription contains a free-text description of the study.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **GlobalVariables**

Top Elements
All Elements
Tree

ODM

ProtocolName

Protocol contains the sponsor's name for the protocol.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **GlobalVariables**

Top Elements
All Elements
Tree

ODM

Locale

Locale contains the name of a geographic locale of the study.

Content:

EMPTY

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID   ID   *#REQUIRED*
Name CDATA *#REQUIRED*

Containing Elements:

- **BasicDefinitions**

Top Elements
All Elements
Tree

ODM

TimeZone

TimeZone contains the name of a timezone used in the study (e.g., EST).

Content:

EMPTY

Attributes:

TimeZones define a set of timezones for use in the study. Because there is no generally accepted standard for timezone definitions, or for the names of timezones, facilities are provided in this element for defining timezone names and definitions for use in a study.

There are approximately 24 * 3 timezones, reflecting the 24 hour divisions and Northern, Equatorial, and Southern locations which affect daylight savings time). There are some oddball timezones, however, that have fractional (half-hour) offsets, unexpected start times for daylight savings, etc. Timezone definitions are a political, not a scientific, concept and there are a large number of anomalies.

The main issue in defining timezones is defining the start and end of daylight savings time (DST). The timezone parameters starting with DST relate to this computation.

BaseOffset::Amount to add to UTC to get local time (not including daylight savings adjustment).

DSTAdjust::Amount to add to local time to adjust for daylight savings.

DSTEndDOW::Daylight savings ending day of week.

DSTEndDay::Daylight savings ending day.

DSTEndHour::Daylight savings ending hour.

DSTEndMonth::Daylight savings ending month.

DSTStartDOW::Daylight savings start day of week.

DSTStartDay::Daylight savings start day.

DSTStartHour::Daylight savings start hour.

DSTStartMonth::Daylight savings start month.

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

BaseOffset	CDATA	*#REQUIRED*
DSTAdjust	CDATA	*#IMPLIED*
DSTEndDOW	CDATA	*#IMPLIED*
DSTEndDay	CDATA	*#IMPLIED*
DSTEndHour	CDATA	*#IMPLIED*
DSTEndMonth	CDATA	*#IMPLIED*
DSTStartDOW	CDATA	*#IMPLIED*
DSTStartDay	CDATA	*#IMPLIED*
DSTStartHour	CDATA	*#IMPLIED*
DSTStartMonth	CDATA	*#IMPLIED*

ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **BasicDefinitions**

Top Elements
All Elements
Tree

ODM

MeasurementUnit

Collection measurement units for a data item (e.g., kg, cm...)

Content:

([Symbol](#))

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

BaseUnitID::Reference to a MeasurementUnit that serves as a base for a set of related units (i.e., gram is a base unit for kilogram, microgram...)

BaseUnitID	[IDREF](#)	*#REQUIRED*
ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **BasicDefinitions**

Top Elements
All Elements
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[ODM](#)

Symbol

MeasurementUnit representation when shown on the screen.

Content:

(<u>TranslatedText</u>*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **MeasurementUnit**

Top Elements
All Elements
Tree

ODM

TranslatedText

Defines the text to be presented for a particular Language and Locale. Supports translation of Item questions, Error Messages, CodeNames.

Content:

```
(#PCDATA)
```

Attributes:

LanguageID::Reference to a Language element.

LocaleID::Reference to a Locale element.

LanguageID	IDREF	*#REQUIRED*
LocaleID	IDREF	*#REQUIRED*

Containing Elements:

- **Decode**
- **ErrorMessage**
- **Question**
- **Symbol**

Top Elements
All Elements
Tree

ODM

Decode

The decoded value associated with a code

Content:

(<u>TranslatedText</u>+)

Attributes:

No ATTRIBUTES

Containing Elements:

- **CodeListItem**

Top Elements
All Elements
Tree

ODM

CodeListItem

Defines an individual codelist item (i.e., a name and a code).

Content:

([Decode](#))

Attributes:

ID::Unique internal identifier for this element.

CodedValue::Code used for the CodeListItem (this is the code, not the user-visible decoded value)

CodedValue CDATA *#REQUIRED*
ID   ID   *#REQUIRED*

Containing Elements:

- **CodeList**

Top Elements
All Elements
Tree

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CodeList

Defines a discrete set of permitted values for an item as name-value pairs.

Content:

([CodeListItem](#)*)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **MetaDataVersion**

Top Elements
All Elements
Tree

ODM

MetaDataVersion

The metadata for a study is defined in a series of one or more MetaDataVersion elements.

Through this mechanism (multiple MetaDataVersion elements), the DTD supports the representation of incrementally deployed "mid-study changes", and thus can handle a situation where multiple versions of the metadata are being used simultaneously (perhaps due to delays in IRB approval at various sites). Each collected piece of data contains keys (reference identifiers) that unambiguously indicate which version of the metadata was actually used to collect it.

The way metatdata versioning works is as follows. An individual Study document may contain multiple MetaDataVersions, reflecting one or more mid-stream study design changes. The initial version contains a full set of metadata; each subsequent version contains only modified or newly added metadata elements. For the new version to reflect an actual change, there must be at least a StudyProtocol element and at least one StudyEvent defined in the modified metadata version. Then, at each level, the new or modified elements point to the unmodified elements (in the previous versions) using the original reference identifiers, as well as any new or modified elements in the latest version.

This approach is used to allow the older versions of the metadata to remain intact, while simultaneously providing a concise way to represent changes. The approach taken means that a small change at the bottom level (e.g., CodeList or Item) will force creation of (and replacement by) new versions of containing elements at each level up through the top of the hierarchy.

On the other hand, a change in a StudyEvent to add a new Form, would only require a redefinition of the modified StudyEvent and the definition of the new Form (which could potentially be made up entirely of pre-existing elements in pre-existing versions of the metadata).

Content:

(StudyProtocol,StudyEvent+,Form+,ItemGroup+,Item+,CodeList*, Presentation*)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **Study**

Top Elements
All Elements
Tree

ODM

StudyProtocol

StudyProtocol lists the set of StudyEvents that are used in the Study. In this version it does not attempt to define the schedule, or repeat structure of those events.

Content:

(StudyEventRef*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **MetaDataVersion**

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StudyEventRef

Element containing a reference to a StudyEvent.

Content:

`EMPTY`

Attributes:

StudyEventID::Reference to a StudyEvent element.

StudyEventID IDREF *#REQUIRED*

Containing Elements:

- **StudyProtocol**

Top Elements
All Elements
Tree

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StudyEvent

A StudyEvent is a defined event that takes place during the study (e.g., a visit).

Content:

([FormRef](#)+)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **MetaDataVersion**

Top Elements
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FormRef

Element containing a reference to a Form.

Content:

`EMPTY`

Attributes:

FormID::Reference to a Form element.

ActualTime	CDATA	*IMPLIED*
FormID	[IDREF](#)	*REQUIRED*

Containing Elements:

- **StudyEvent**

Top Elements
All Elements
Tree

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Form

A Form is analogous to a page in a paper CRF book. It is a data capture unit contained within a StudyEvent, and generally collects a set of logically and temporally related information together with an electronic signature.

Content:

([ItemGroupRef](#)+, [ArchiveLayout](#)*)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID   ID   *#REQUIRED*
 Name CDATA *#REQUIRED*

Containing Elements:

- **[MetaDataVersion](#)**

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[All Elements](#)
[Tree](#)

[ODM](#)

ItemGroupRef

Element containing a reference to an ItemGroup.

Content:

EMPTY

Attributes:

ItemGroupRef::Reference to an ItemGroup element.

 ItemGroupID IDREF *#REQUIRED*

Containing Elements:

- **Form**

Top Elements
All Elements
Tree

[ODM](ODM)

ItemGroup

An ItemGroup is a closely related set of items that is generally analyzed together. All items in an ItemGroup will have the same "repeating" behavior (for example, each row might represent a patient, a patient visit, an occurrence, etc.). In some CDM systems, ItemGroups are referred to as "panels" or "tables".Examples of item groups include demographic, vital signs, concomitant medications, medical history, physical exam.

Content:

(ItemRef+)

Attributes:

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

ID	ID	*#REQUIRED*
Name	CDATA	*#REQUIRED*

Containing Elements:

- **MetaDataVersion**

Top Elements
All Elements
Tree

[ODM](ODM)

ItemRef

Element containing a reference to an Item.

Content:

```
EMPTY
```

Attributes:

ItemID::Reference to an Item element.

 ItemID [IDREF](#) *#REQUIRED*

Containing Elements:

- **ItemGroup**

Top Elements
All Elements
Tree

[ODM](#)

Item

An Item represents an individual clinical data item, including name and datatype, along with optional associated CodeLists, MeasurementUnits, and range check information. Items also include an associated label or question. CodeLists, questions, and system messages provide for translation into multiple languages (as defined by Language and Locale).

Content:

(Question?,CodeListRef?,RangeCheck*,MeasurementUnitRef*)

Attributes:

CodeListID::Reference to a CodeList if this Item is used to collect coded data.

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

DataType::Intended data type of the Item, can be one of: integer float date datetime time text

Length::Maximum length of the Item in characters.

SignificantDigits::Number of significant digits to collect for Item.

CodeListID	IDREF	*#IMPLIED*
DataType	(integer | date | datetime | time | float | text)	*#REQUIRED*
ID	ID	*#REQUIRED*
Length	CDATA	*#IMPLIED*
Name	CDATA	*#REQUIRED*
SignficantDigits	CDATA	*#IMPLIED*

Containing Elements:

- **MetaDataVersion**

Top Elements
All Elements
Tree

ODM

Question

Text of a question or label related to an Item as presented on paper or screen. A Question may contain zero or more translation versions (zero because some items are not associated with a question).

Content:

(TranslatedText*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **Item**

Top Elements
All Elements
Tree

ODM

CodeListRef

Element containing a reference to a CodeList.

Content:

EMPTY

Attributes:

CodeListRef::Reference to a CodeList element.

 CodeListID IDREF *#REQUIRED*

Containing Elements:

- **Item**

Top Elements
All Elements
Tree

ODM

RangeCheck

One-sided check of an entered value (a full range check will require two RangeCheck elements, one for the lower bound and one for the upper bound).

Content:

(<u>CheckValue</u>*,<u>ErrorMessage</u>?)

Attributes:

Comparitor::Comparison operator used to compare item with CheckValue (order is: item comparitor checkvalue)

SoftHard::Whether the RangeCheck is intended to produce a hard (entry not allowed) or soft (warning) error.

Comparator	(LT | LE | GT | GE | EQ | NE)	*#REQUIRED*
SoftHard	(Soft | Hard)	*#REQUIRED*

Containing Elements:

- **Item**

Top Elements
All Elements
Tree

ODM

CheckValue

Comparison value used in a RangeCheck.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **RangeCheck**

Top Elements
All Elements
Tree

ODM

ErrorMessage

Error message to be generated when a range check is violated.

Content:

(TranslatedText*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **RangeCheck**

Top Elements
All Elements
Tree

ODM

MeasurementUnitRef

Element containing a reference to a MeasurementUnit.

Content:

```
EMPTY
```

Attributes:

MeasurementUnitID::Reference to a MeasurementUnit element.

 MeasurementUnitID [IDREF](#) *#REQUIRED*

Containing Elements:

- **FlatItemData**
- **HierItemData**
- **Item**

Top Elements
All Elements
Tree

[ODM](#)

FlatItemData

An individual clinical data value in the flat representation.

Content:

(PatientKey,StudyEventKey,FormKey,ItemGroupKey,ItemKey,Value?,
MeasurementUnitRef?,Comment?,Signature?,ReasonForChange?)

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatData**

Top Elements
All Elements
Tree

ODM

PatientKey

Unique key used to refer to a patient.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **FlatPatientData**
- **FlatStudyEventData**
- **HierPatientData**

Top Elements
All Elements
Tree

ODM

FlatFormData

Data collected about a Form (page) in the flat representation.

Content:

(PatientKey,StudyEventKey,FormKey,Comment?,Signature, ReasonForChange?)

Attributes:

ArchiveLayoutID::Link to ArchiveLayout used to collect FormData.

ArchiveLayoutID IDREF *#IMPLIED*

Containing Elements:

- **FlatData**

Top Elements
All Elements
Tree

ODM

StudyEventKey

Unique key used to refer to a StudyEvent.

Content:

```
EMPTY
```

Attributes:

StudyEventID::Reference to a StudyEvent element.

StudyEventRepeatKey::Key used to distinguish between repeats of a StudyEvent.

StudyEventID	[IDREF](#)	*#REQUIRED*
StudyEventRepeatKey	CDATA	*#IMPLIED*

Containing Elements:

- **[FlatFormData](#)**
- **[FlatItemData](#)**
- **[FlatItemGroupData](#)**
- **[FlatStudyEventData](#)**
- **[HierStudyEventData](#)**

[Top Elements](#)
[All Elements](#)
[Tree](#)

[ODM](#)

Presentation

Presentation defines how information about the study is presented to the user of a system. Presentation is presently undefined in the CDISC DTD.

Content:

`(#PCDATA)`

Attributes:

LocaleID::Identifies Locale appropriate to Presentation

 LocaleID [IDREF](#) *#IMPLIED*

Containing Elements:

- **MetaDataVersion**

Top Elements
All Elements
Tree

ODM

ArchiveLayout

Defines the screen layout used to collect the data so that it is available to the user of an archive file.

Content:

`EMPTY`

Attributes:

PdfFileName::Name of a Adobe PDF file containing the screen layout.

PresentationID::Links ArchiveLayout to a specific Presentation.

ID::Unique internal identifier.

ID	ID	*#REQUIRED*
PdfFileName	CDATA	*#REQUIRED*
PresentationID	IDREF	*#IMPLIED*

Containing Elements:

- **Form**

Top Elements
All Elements
Tree

ODM

FlatItemGroupData

Data collected about an ItemGroup (group of related items) in the flat representation.

Content:

(PatientKey,StudyEventKey,FormKey,ItemGroupKey,Comment?,
Signature?,ReasonForChange?)

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatData**

Top Elements
All Elements
Tree

ODM

FormKey

Unique key used to refer to a Form.

Content:

`EMPTY`

Attributes:

FormID::Reference to a form.

FormRepeatKey::Key used to distinguish between repeats of a Form.

FormID	[IDREF](#)	*#REQUIRED*
FormRepeatKey	CDATA	*#IMPLIED*

Containing Elements:

- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **HierFormData**

Top Elements
All Elements
Tree

ODM

HierFormData

Data collected about a Form (page).

Content:

(FormKey,Comment?,HierItemGroupData*,Signature,ReasonForChange?)

Attributes:

ArchiveLayoutID::Link to ArchiveLayout used to collect FormData.

ArchiveLayoutID IDREF *#IMPLIED*

Containing Elements:

- **HierStudyEventData**

Top Elements
All Elements
Tree

ODM

Comment

Investigator comment.

Content:

(CommentText)

Attributes:

SponsorOrSite::Whether the comment was created by a clinical site or by the study sponsor.

 SponsorOrSite (Sponsor | Site) *#IMPLIED*

Containing Elements:

- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **FlatPatientData**
- **FlatStudyEventData**
- **HierFormData**
- **HierItemData**
- **HierItemGroupData**
- **HierPatientData**
- **HierStudyEventData**

Top Elements
All Elements
Tree

ODM

CommentText

Text of a comment.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **Comment**

Top Elements
All Elements
Tree

ODM

FlatPatientData

A FlatPatientData element defines a patient in the flat representation of data.

Content:

(PatientKey,Comment?,Signature?,ReasonForChange?)

Attributes:

Information about a patient in a study.

DeleteFlag::Whether this patient has been deleted.

DOB::Date of birth of this patient.

EnrollDate::Enrollment date of this patient.

DateOnTreatment::Date of first treatment of this patient.

Sex::Sex of this patient.

Initials::Initials of this patient.

Patientid::Sponsor's patient id for this patient.

RandDate::Randomization date of this patient.

Randid::Randomization code assigned to this patient.

TerminationDate::Study termination date of this patient.

DOB	CDATA	*#IMPLIED*
DateOnTreatment	CDATA	*#IMPLIED*
DeleteFlag	(Yes | No)	*#IMPLIED*
EnrollDate	CDATA	*#IMPLIED*
Initials	CDATA	*#IMPLIED*
Patientid	CDATA	*#REQUIRED*
RandDate	CDATA	*#IMPLIED*
Randid	CDATA	*#IMPLIED*
Sex	(M | F)	*#IMPLIED*
TerminationDate	CDATA	*#IMPLIED*

Containing Elements:

- **FlatData**

Top Elements
All Elements
Tree

ODM

Signature

Actual electronic signature information.

Content:

(CryptoBindingManifest?,UserRef,LocationRef,SignatureDefRef, DateTimeStamp)

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **FlatPatientData**
- **FlatStudyEventData**
- **HierFormData**
- **HierItemData**
- **HierItemGroupData**
- **HierPatientData**
- **HierStudyEventData**

Top Elements
All Elements
Tree

ODM

CryptoBindingManifest

Manifest related to a digital signature.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **Signature**

Top Elements
All Elements
Tree

ODM

UserRef

Element containing a reference to a User.

Content:

EMPTY

Attributes:

UserID::Reference to a User element.

UserID IDREF *#REQUIRED*

Containing Elements:

- **Signature**

Top Elements
All Elements
Tree

ODM

LocationRef

Container for reference to a Location element.

Content:

EMPTY

Attributes:

LocationID::Reference to a Location element.

 LocationID [IDREF](#) *#REQUIRED*

Containing Elements:

- **Signature**
- **User**

Top Elements
All Elements
Tree

ODM

Location

A set of Locations (primarily clinical research sites) defined for a study.

Content:

([MetaDataVersionRef](#))

Attributes:

Locations are places like sponsors and clinical research sites.

ID::Unique internal identifier for this element.

Name::User-visible name for this element.

LocationType::One of: Site, Sponsor, CRO, Lab, Other

ID	ID	*#REQUIRED*
LocationType	(Sponsor | Site | CRO | Lab | Other)	*#IMPLIED*
Name	CDATA	*#REQUIRED*
TimeZoneID	IDREF	*#REQUIRED*

Containing Elements:

- **AdminData**

Top Elements
All Elements
Tree

ODM

MetaDataVersionRef

Element containing a reference to a MetaDataVersion.

Content:

```
EMPTY
```

Attributes:

MetaDataVersionID::Reference to a MeasurementDataVersion element.

MetaDataVersionID [IDREF](#) *#REQUIRED*

Containing Elements:

- **[Location](#)**

[Top Elements](#)
[All Elements](#)
[Tree](#)

[ODM](#)

SignatureDef

Defines the context of a signature, including meaning as required by FDA regulations and guidelines.

Content:

(Meaning,LegalReason)

Attributes:

ID::Unique internal identifier for this element.

Methodology::Whether the signature is digital (based on cryptography) or electronic (not based on cryptography).

| **ID** | ID | *#REQUIRED* |
| **Methodology** | (Digital \| Electronic) | *#IMPLIED* |

Containing Elements:

- **AdminData**

Top Elements
All Elements
Tree

ODM

Meaning

Meaning of a signature (e.g., authorship, approval).

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **SignatureDef**

Top Elements
All Elements
Tree

ODM

LegalReason

Responsibility statement associated with a signature (e.g., "Signing accepts responsibility for the data entered").

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **SignatureDef**

Top Elements
All Elements
Tree

ODM

SignatureDefRef

Element containing a reference to a SignatureDef (the definition of a signature, not the signature itself).

Content:

`EMPTY`

Attributes:

SignatureDefID::Reference to a SignatureDef element.

SignatureDefID [IDREF](#) *#REQUIRED*

Containing Elements:

- **[Signature](#)**

[Top Elements](#)
[All Elements](#)
[Tree](#)

[ODM](#)

DateTimeStamp

Use ISO date format

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **Signature**

Top Elements
All Elements
Tree

ODM

ReasonForChange

Contains a user-supplied reason for a data change.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatFormData**
- **FlatItemData**
- **FlatItemGroupData**
- **FlatPatientData**
- **FlatStudyEventData**
- **HierFormData**
- **HierItemData**
- **HierItemGroupData**
- **HierPatientData**
- **HierStudyEventData**

Top Elements
All Elements
Tree

ODM

FlatStudyEventData

Data collected about a StudyEvent (visit) in the flat representation. The DTD supports repeating events (for example, when the same set of information is collected for a series of patient visits).

Content:

(PatientKey,StudyEventKey,Comment?,Signature?,ReasonForChange?)

Attributes:

Data about an individual study event in the flat representation.

ExpectedTime::Planned time of occurrence of the event.

ActualTime::Actual time of occurrence of the event.

DeleteFlag::Whether the StudyEvent has been deleted.

ActualTime	CDATA	*#IMPLIED*
DeleteFlag	(Yes | No)	*#IMPLIED*
ExpectedTime	CDATA	*#IMPLIED*

Containing Elements:

- **FlatData**

Top Elements
All Elements
Tree

ODM

FlatData

Content:

(<u>FlatPatientData</u>*,<u>FlatStudyEventData</u>*,<u>FlatFormData</u>*,
<u>FlatItemGroupData</u>*,<u>FlatItemData</u>*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **Study**

Top Elements
All Elements
Tree

ODM

HierItemGroupData

Data collected about an ItemGroup (group of related items).

Content:

(ItemGroupKey , Comment ?, HierItemData *, Signature ?, ReasonForChange ?)

Attributes:

No ATTRIBUTES

Containing Elements:

- **HierFormData**

Top Elements
All Elements
Tree

ODM

ItemGroupKey

Unique key used to refer to an ItemGroup.

Content:

EMPTY

Attributes:

ItemGroupID::Key for an ItemGroup.

ItemGroupRepeatKey::Key used to distinguish repeats of an ItemGroup.

ItemGroupID	[IDREF](#)	*#REQUIRED*
ItemGroupRepeatKey	CDATA	*#IMPLIED*

Containing Elements:

- **FlatItemData**
- **FlatItemGroupData**
- **HierItemGroupData**

Top Elements
All Elements
Tree

[ODM](#)

HierItemData

An individual clinical data value.

Content:

(ItemKey,Value?,MeasurementUnitRef?,Comment?,Signature?, ReasonForChange?)

Attributes:

No ATTRIBUTES

Containing Elements:

- **HierItemGroupData**

Top Elements
All Elements
Tree

ODM

ItemKey

Unique key used to refer to an Item.

Content:

```
EMPTY
```

Attributes:

ItemID::Reference to an Item element.

 ItemID [IDREF](#) *#REQUIRED*

Containing Elements:

- **FlatItemData**
- **HierItemData**

Top Elements
All Elements
Tree

[ODM](#)

Value

Data value collected for an Item.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **FlatItemData**
- **HierItemData**

Top Elements
All Elements
Tree

ODM

HierStudyEventData

Data collected about a StudyEvent (visit). The DTD supports repeating events (for example, when the same set of information is collected for a series of patient visits).

Content:

(StudyEventKey , Comment ?, HierFormData *, Signature ?, ReasonForChange ?)

Attributes:

Data about an individual study event.

ExpectedTime::Planned time of occurrence of the event.

ActualTime::Actual time of occurrence of the event.

DeleteFlag::Whether the StudyEvent has been deleted.

ActualTime	CDATA	*#IMPLIED*
DeleteFlag	(Yes | No)	*#IMPLIED*
ExpectedTime	CDATA	*#IMPLIED*

Containing Elements:

- **HierPatientData**

Top Elements
All Elements
Tree

ODM

HierPatientData

A HierPatientData element defines a patient.

Content:

([PatientKey](), [Comment]()?, [HierStudyEventData]()*, [Signature]()?, [ReasonForChange]()?)

Attributes:

Information about a patient in a study.

DeleteFlag::Whether this patient has been deleted.

DOB::Date of birth of this patient.

EnrollDate::Enrollment date of this patient.

DateOnTreatment::Date of first treatment of this patient.

Sex::Sex of this patient.

Initials::Initials of this patient.

Patientid::Sponsor's patient id for this patient.

RandDate::Randomization date of this patient.

Randid::Randomization code assigned to this patient.

TerminationDate::Study termination date of this patient.

DOB	CDATA	*#IMPLIED*
DateOnTreatment	CDATA	*#IMPLIED*
DeleteFlag	(Yes | No)	*#IMPLIED*
EnrollDate	CDATA	*#IMPLIED*
Initials	CDATA	*#IMPLIED*
Patientid	CDATA	*#REQUIRED*
RandDate	CDATA	*#IMPLIED*
Randid	CDATA	*#IMPLIED*
Sex	(M | F)	*#IMPLIED*
TerminationDate	CDATA	*#IMPLIED*

Containing Elements:

- **HierData**

Top Elements
All Elements
Tree

ODM

HierData

Content:

(<u>HierPatientData</u>*)

Attributes:

No ATTRIBUTES

Containing Elements:

- **Study**

Top Elements
All Elements
Tree

<u>ODM</u>

DisplayName

System user name as displayed.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

FullName

Full printed name of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

FirstName

First name of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

LastName

Last name of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Organization

Name of the organization to which a system user belongs.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

City

City name component of system user's address.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

StateProv

State or province name component of system user's address.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

Country

Country name component of system user's address.

Content:

EMPTY

Attributes:

Name::ISO 3166 2-letter country code. There seems to be a problem here: BY is the 2-letter code for both BELARUS and BYELORUSSIAN SSR.

Name	(AF | AL | DZ | AS | AD | AO | AI | AQ | AG | AR | AM | AW | AU | AT | AZ | BS | BH | BD | BB | BY | BE | BZ | BJ | BM | BT | BO | BA | BW | BV | BR | IO | BN | BG | BF | BI | KH | CM | CA | CV | KY | CF | TD | CL | CN | CX | CC | CO | KM | CG | CK | CR | CI | HR | CU | CY | CZ | DK | DJ | DM | DO | TP | EC | EG | SV | GQ | EE | ET | FK | FO | FJ | FI | FR | FX | GF | PF | TF | GA | GM | GE | DE | GH | GI | GR | GL | GD | GP | GU | GT | GN | GW | GY | HT | HM | HN | HK | HU | IS | IN | ID | IR | IQ | IE | IL | IT | JM | JP | JO | KZ | KE | KI | KP | KR | KW | KG | LA | LV | LB | LS | LR | LY | LI | LT | LU | MO | MG | MW | MY | MV | ML | MT | MH | MQ | MR | MU | YT | MX | FM | MD | MC | MN | MS | MA | MZ | MM | NA | NR | NP | NL | AN | NC | NZ | NI | NE | NG | NU | NF | MP | NO | OM | PK | PW | PA | PG | PY | PE | PH | PN | PL | PT | PR | QA | RE | RO | RU | RW | KN | LC | VC | WS | SM | ST | SA | SN | SC | SL | SG | SK | SI | SB | SO | ZA | ES | LK | SH | PM | SD | SR | SJ | SZ | SE | CH | SY | TW | TJ | TZ | TH | TG | TK | TO | TT | TN | TR | TM | TC | TV | UG | UA | AE | GB | US | UM | UY | UZ | VU | VA | VE | VN | VG | VI | WF | EH | YE | YU | ZR | ZM | ZW)	*#IMPLIED*

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

PostalCode

Postal code component of system user's address.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

OtherText

Undefined additional component of a system user's address.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **Address**

Top Elements
All Elements
Tree

ODM

Email

Email address of a system user.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Picture

Picture of a system user.

Content:

EMPTY

Attributes:

PictureFileName::Name of an external file containing an image.

ImageType::Image type (TIFF, GIF, JPEG, etc.)

ImageType   CDATA *#IMPLIED*
PictureFileName CDATA *#REQUIRED*

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Pager

Pager number of a system user.

Content:

```
(#PCDATA)
```

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Fax

Fax number of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Phone

Telephone number of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM

Certificate

Digital signing certificate of a system user.

Content:

`(#PCDATA)`

Attributes:

No ATTRIBUTES

Containing Elements:

- **User**

Top Elements
All Elements
Tree

ODM