CDISC CTR-XML Specification

Version 1.0

Prepared by the

XML Technologies Team

Notes to Readers

- This is the specification for Version 1.0 of the CDISC CTR-XML standard.
- CTR-XML is based on ODM v1.3.2.1

Revision History

Date	Version	Summary of Changes
2016-03-28	1.0 Provisional	Updates to reflect public comments.
2015-10-28	1.0 Draft	Version 1.0 for public comment.

See Appendix D for Representations and Warranties, Limitations of Liability, and Disclaimers.

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1 Introduction

1.1 Purpose of this Document

This specification describes the CTR-XML (Clinical Trial Registry) model, a model based on the CDISC Operational Data Model (ODM), and how it can be used for clinical trial registry submissions to the World Health Organization (WHO), the European Medicines Agency (EMA) EudraCT Registry, and the United States' ClinicalTrials.gov clinical trials registry. The current version of this standard is focused on submissions of the study design subset and does not include submissions of clinical trials results.

The CTR–XML standard does not provide a unified message that can be submitted directly to all the registries. Rather, it provides an approach for generating harmonized messages to each of the three agencies mentioned here.

The intent of the CTR-XML standard is to provide technology vendors with the ability to implement tools that support a "write once, use many times" solution based on a single XML file that holds the information needed to generate submissions for multiple clinical trial registries.

1.2 CTR-XML Release Package

This document is accompanied by a set of XML-Schemas, containing:

- The core ODM v1.3.2 XML-Schemas
- The SDM-XML v1.0 XML-Schemas
- The XML-Schemas for CTR extension elements and attributes (ctr-ns.xsd)
- A subset of EudraCT XML-Schemas (v.10) which for a small number of CTR elements are needed to "plug in" EudraCT-specific data structures into ODM.
- A set of XML schemas for integrating SDM-XML and CTR and EudraCT schemas into core ODM as an extension

The CTR-XML release package includes:

- CTR-XML v1.0 specification (this document)
- The set of XML schemas listed above.
- CTR-XML v1.0 example files

1.3 CTR-XML for Clinical Trails Registration

1.3.1 WHO

The World Health Organization (WHO) provides the WHO International Clinical Trials Registry Platform (ICTRP) as a resource for making information about interventional clinical trials available to anyone involved in health care decision making. The WHO ICTRP has as its basis an internationally-agreed set of information about the design, conduct, and administration of clinical trials. This set of information, known as the Trial Registration Data Set (TRDS) has 20 items. The WHO ICTRP dataset is described at http://www.who.int/ictrp/network/trds/en/.

1.3.2 EudraCT

The European Union (EU) provides a registry, known as the EU Clinical Trials Register or EudraCT, that contains information on interventional clinical trials on medicines conducted in the European Union or the European Economic Area (EEA). EudraCT is a primary registry in the WHO registry network. The *EudraCT protocol-related data dictionary* is available in Excel form, which is downloadable from https://eudract.ema.europa.eu/protocol.html. Links to many relevant directives, regulations, and guidances can be found at http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

1.3.3 ClinicalTrials.Gov

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human subjects conducted around the world. It is operated as a service of the United States National Institutes of Health. The protocol for submitting protocol information to this registry is described by the ClinicalTrials.gov Protocol Data Element Definitions at https://prsinfo.clinicaltrials.gov/definitions.html. A description of the policies and laws related to the development and use of ClinicalTrials.gov can be found at https://clinicaltrials.gov/ct2/about-site/history.

1.4 CDISC

The Clinical Data Interchange Standards Consortium (CDISC) is a non-profit organization whose mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. More information on CDISC may be found at http://www.cdisc.org.

1.5 Relationships to Other CDISC Standards

1.5.1 Operational Data Model (ODM)

The CTR-XML standard is based on the CDISC Operational Data Model (ODM) v1.3.2 XML schema. ODM is a vendor-neutral, platform-independent format for the interchange and archiving of clinical study data. The model includes clinical data along with its associated metadata, administrative data, reference data, and audit information. ODM includes all of the information that needs to be shared among different software systems during study setup, operation, analysis, and submission or for long-term retention as part of a study archive. ODM has been embraced by a broad range of clinical development organizations, and a number of vendors provide software applications and tools that use ODM. The current version of the ODM standard is available at http://www.cdisc.org/odm.

One of the features of the ODM is a standardized mechanism for defining schema extensions to provide functionality needed to support interchange requirements for specialized use cases.

To address the specific needs of data transmission in support of submissions to trial registries, CDISC has developed the CTR-XML model, which is implemented as a set of extensions to the base ODM schema. These extensions follow the guidelines for vendor extensions provided in the ODM specification and comply with the W3C XML Schema 1.0 specification. The XML schema files for the CTR-XML standard are available online at http://www.cdisc.org/CTR-XML.

While this document is intended to be comprehensible to readers with minimal technical knowledge of the ODM and XML, understanding this document alone is not a substitute for knowledge of the ODM. This document should be used in close concert with the current version of the ODM specification as well as current versions of the relevant CDISC data and metadata standards. Reading the ODM specification Introduction (Section 1), the Study section (3.1.1) and the AdminData section (3.1.2) at a minimum, is recommended. The ODM specification package, including the relevant schemas, is available online at http://www.cdisc.org/odm.

Numerous examples of XML fragments appear in this document. Many of these examples are provided as XML files and can be downloaded from the CDISC website (http://www.cdisc.org/CTR-XML).

1.5.2 SDM-XML

The Study Design Model (SDM-XML) uses extensions to the CDISC Operational Data Model (ODM) XML schema to provide an XML representation of the information included in the CDISC SDTM Trial Design model. Use of SDM-XML helps sponsor organizations improve the end-to-end efficiency of clinical trials data management by providing a standard for representing the structure, workflow, and timing of a study design.

1.5.3 CDISC Controlled Terminology

The CTR-XML standard uses CDISC Controlled Terminology to provide curated, standardized value lists that improve the consistency of the CTR-XML content. CDISC Controlled Terminology is used throughout the clinical research process, from data collection through analysis and submission.

Numerous examples demonstrating the use of controlled terminology terms are included in this specification. However, this document does not contain any definitive controlled terminology. Since the controlled terminology is published quarterly, new values may be added to a given value list over time. Some examples may use values that appear to be controlled terminology, but which are actually generic or "best guess" placeholders.

Readers should consult the current CDISC Controlled Terminology (available at http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc) as the ultimate authority for correct controlled terminology codelists and values.

1.5.4 Proposed Workflow

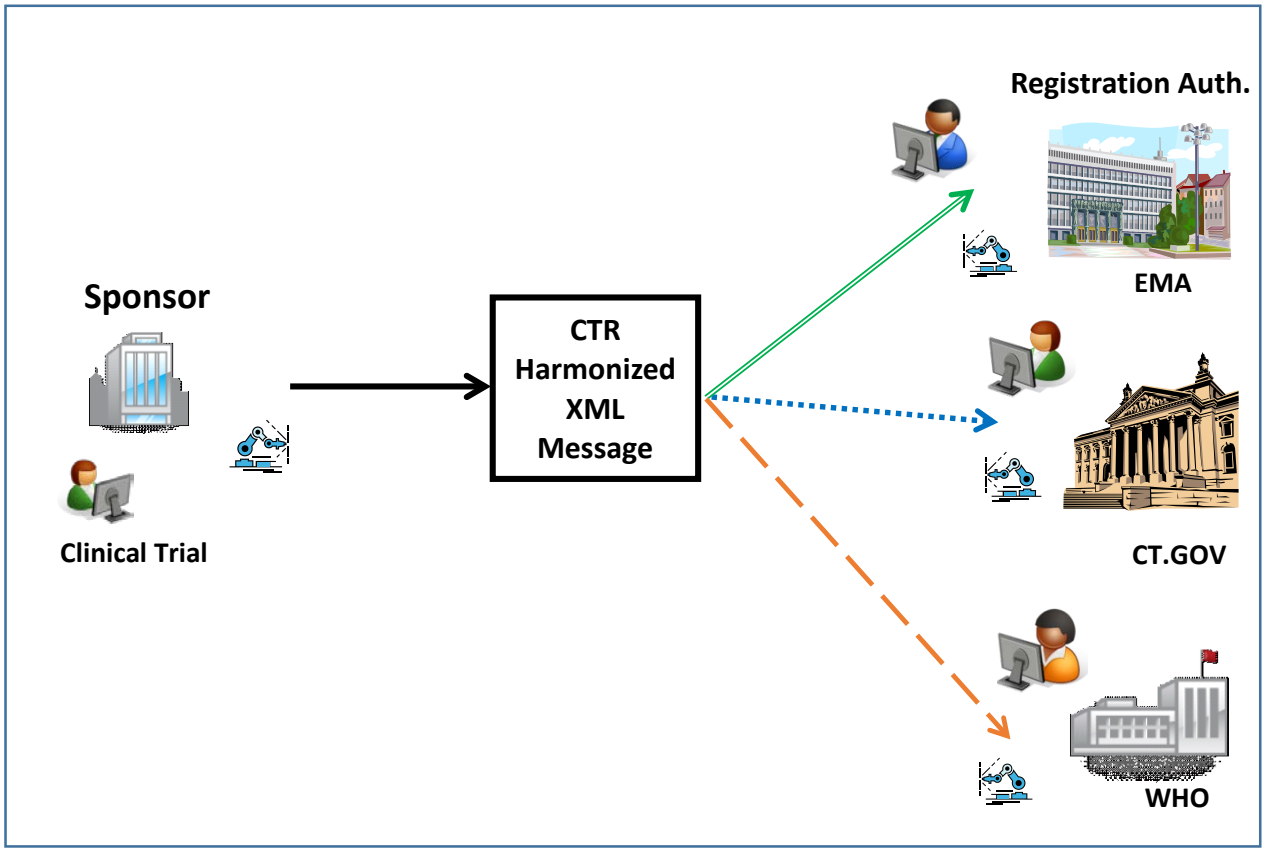

Figure 1: CTR Data Flow

A high-level view of how this standard will be used is show in Figure 1. The message format described in this document will provide sponsors a simpler, more efficient way to submit trial registration information simultaneously to multiple registration authorities. Since registry submissions must be periodically updated to reflect changes (e.g., in recruitment status), this approach allows information to be updated in one place.

A single clinical trial registration XML message format that accommodates the varying requirements of key registries allows software vendors to build tools that map information from this common format to registry specific XML messages.

2 Abbreviations and References

2.1 Abbreviations and Terms

CTR	Clinical Trial Registry
EEA	European Economic Area
FDA	United States Food and Drug Administration
ICH	International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use.
IMP	Investigational Medicinal Product.
ICTRP	International Clinical Trials Registry Platform
ODM	Operational Data Model – developed by CDISC as an XML format for the transmission and archival of clinical trials data and metadata.
OID	ODM element identifier.
SDM	Study Design Model.
SDTM	Study Data Tabulation Model - developed by CDISC for the purpose of submitting study data tabulations to the United States Food and Drug Administration.
TRDS	Trial Registration Data Set
URI	Uniform Resource Identifier - a string of characters used to identify a resource on the internet
URL	Uniform Resource Locator
W3C	World Wide Web Consortium
XLink	XML Linking Language – developed by the W3C
XML	Extensible Markup Language - developed by the W3C

2.2 References

The documents referenced during the development of this CTR-XML Specification may be accessed via the links provided below.

- CDISC website
  http://www.cdisc.org
- ODM Version 1.3.2
  http://www.cdisc.org/odm
- WHO Trial Registration Data Set – TRDS
  http://www.who.int/ictrp/network/trds/en/
- EudraCT Protocol related documentation (EudraCT protocol related data dictionary)
  https://eudract.ema.europa.eu/protocol.html
- ClinicalTrials.gov Protocol Data Element Definitions
  https://prsinfo.clinicaltrials.gov/definitions.html

3 Conformity and General Issues

This section supplements the corresponding section, "General Issues", of the ODM v1.3.2 specification.

All conformity requirements described in the ODM v1.3.2 specification are also applicable to CTR-XML files unless stated otherwise.

3.1 File Conformity

Throughout this document, the following conventions are used for namespaces:

- ODM elements and attributes are in the default namespace (i.e., they have no namespace prefix),
- CTR-XML elements use the namespace prefix "ctr",
- Attributes in the CTR namespace http://www.cdisc.org/ns/ctr/v1.0 should use the prefix "ctr" if they appear within ODM or SDM-XML elements.
- Elements defined in the EudraCT XML schemas use the namespace prefix "ct",
- Attributes for elements defined in the EudraCT XML schemas use the namespace prefix "ct" if they appear within ODM, SDM-XML, or CTR-XML elements,
- SDM-XML elements use the namespace prefix "sdm",
- SDM-XML attributes use the namespace prefix "sdm" only if they appear within ODM elements,

In the example XML files the prefixes and URI namespace prefixes and URIs used in version 1.0.0 are:

ctr	http://www.cdisc.org/ns/ctr/v1.0
ct	http://eudract.emea.europa.eu/schema/clinical_trial
sdm	http://www.cdisc.org/ns/studydesign/v1.0

Note that these namespace prefixes are used throughout this document and are recommended as a best practice both to make it easier for users to understand and implement, and to aid in the comparison of documents.

Any XML included in a CTR-XML document that is not described in this specification is considered an extension.

Deprecated elements or attributes are not valid for use and are considered errors.

3.2 Document Structure

The order and tree structure of the ODM, SDM-XML, and CTR elements is depicted here.
ODM and SDM-XML elements having CTR attributes are in **bold red**.

For each element, the minimum and maximum number of instances (cardinality) within the parent element is indicated.

```
ODM
   Study
      GlobalVariables   [1..1]
         StudyName   [1..1]
            ctr:StudyNameLocalizations   [0..1]
               TranslatedText   [1..n]
         StudyDescription   [1..1]
         ProtocolName   [1..1]
         ctr:Authorities   [0..1]
            ctr:FDAInformation   [0..1]
            ctr:InstitutionalReviewBoardEthicsCommittee   [0..n]
               ctr:OrganizationRef   [1..1]
            ctr:OversightAuthority   [0..n]
               ctr:OrganizationRef   [1..1]
         ctr:PublicTitle   [0..1]
```

```
      TranslatedText   [1..n]
   ctr:StudyDetailedDescription   [0..1]
      TranslatedText   [1..n]
   ctr:Registrations   [0..1]
      ctr:Registration   [1..n]
   ctr:FundingSupport   [0..1]
      ctr: Sponsor   [0..n]
   ctr:Contacts   [0..1]
      ctr:Contact   [0..n]
BasicDefinitions   [0..1]
   …
MetaDataVersion   [0..n]
   Protocol   [0..1]
      Description   [0..1]
      StudyEventRef   [0..n]
      Alias   [0..n]
      sdm:Summary   [1..1]
         Description   [0..1]
         sdm:Parameter   [0..n]
            sdm:Value   [1..n]
   sdm:InclusionExclusionCriteria   [1..1]
      Description   [0..1]
      sdm:InclusionCriteria   [0..1]
         sdm:Criterion   [1..n]
      sdm:ExclusionCriteria   [0..1]
         sdm:Criterion   [1..n]
   sdm:Structure   [1..1]
      sdm:Epoch   [0..n]
      sdm:Arm   [0..n]
      sdm:CellDef   [0..n]
         sdm:ArmAssociation   [0..1]
            sdm:ArmRef   [1..n]
            ctr:BlindedRole   [0..n]
         sdmSegmentRef   [0..n]
      sdm:SegmentDef   [0..n]
         sdm:ActivityRef   [0..n]
      sdm:ActivityDef   [0..n]
         FormRef   [0..n]
   StudyEventDef   [0..n]
   FormDef   [0..n]
      ItemGroupRef   [0..n]
   ItemGroupDef   [0..n]
      ItemRef   [0..n]
   ItemDef   [0..n]
      CodeListRef   [0..1]
   CodeList   [0..n]
      EnumeratedItem   [0..n]
      CodeListItem   [0..n]
         Decode   [1..1]
      ExternalCodeList   [1..1]
   ConditionDef   [0..n]
   ctr:Recruitment   [0..1]
      ctr:RecruitmentCountries   [1..1]
         ctr:RecruitmentCountry   [1..n]
      ctr:RecruitmentStatus   [1..n]
         ctr:RecruitmentStatusOther   [0..1]
   ctr:Interventions   [0..1]
      ctr:Intervention   [1..n]
         Description   [0..1]
         ctr:InterventionOtherName   [0..n]
   ctr:OutcomeMeasures   [0..1]
      ctr:OutcomeMeasure   [1..n]
         ctr:Timepoint   [1..n]
```

```
            FormalExpression   [0..n]
      ctr:StudyStartDate   [0..1]
      ctr:StudyEndDate   [0..1]
      ctr:StudyEndDatePrimaryOutcome   [0..1]
      ct:medicinal_product_information   [0..1]
         ct:medicinal_product   [0..n]
      ct:population_information   [0..1]
AdminData   [0..1]
   User   [0..n]
      FullName   [0..1]
      Organization   [0..1]
      Email   [0..1]
      ctr:Role   [0..n]
      ctr:OrganizationRef   [0..n]
      ctr:Qualifications   [0..1]
   ctr:Organization   [0..n]
      Address   [0..n]
         StreetName   [0..n]
         City   [0..1]
         StateProv   [0..1]
         Country   [0..1]
         PostalCode   [0..1]
         OtherText   [0..1]
      Email   [0..n]
      Fax   [0..n]
      Certificate   [0..n]
      ctr:Role   [0..n]
   ctr:CentralTechnicalFacilities   [0..1]
      ctr:CentralTechnicalFacility   [1..n]
         ctr:OrganizationRef   [1..1]
         ctr:Contact   [0..1]
         ctr:CentralTechnicalFacilityDuty   [0..n]
   ctr:Networks   [0..1]
      ctr:Network   [1..n]
         ctr:OrganizationRef   [1..1]
         ctr:Contact   [0..1]
         ctr:NetworkActivities   [1..1]
   ctr:SubContractors   [0..1]
      ctr:SubContractor   [1..n]
         ctr:OrganizationRef   [1..1]
         ctr:Contact   [1..1]
         ctr:SubContractorDuty   [0..n]
```

3.3 OIDs

Attributes whose names end with "OID" are used to uniquely identify specific metadata objects. For example, in the CodeList XML element (described in Section 5.3.3.17), the CodeListOID attribute references a specific CodeList in the CTR-XML file containing the Controlled Terminology definition. Although the examples in this document use prefixes in the OIDs to indicate the object type, this is not required. The value of the OID attribute has no meaning by itself.

3.4 Validation of a CTR-XML Document

A valid CTR-XML document must:

- Properly reference versions of the CDISC standards.
- Be well formed and conform to the CTR-XML schemas.
- Meet all of the requirements documented in this specification.

The ctr1-0-0.xsd XML schema should be used to validate CTR-XML documents.

Once a CTR-XML document is valid according to the schema, validation software should consider all CTR-XML requirements included in this specification. These requirements include rules about conditionally required components and other business rules. Schema validation can only enforce some parts of the standard, so this additional level of validation is required to determine whether a CTR-XML document is fully compliant with CTR-XML v1.0.0.

The correct ordering of elements within a document is an absolute requirement for the document to be valid with respect to the CTR-XML schema. The use of an XML schema definition and a validating parser environment make detection of improperly ordered content fairly straightforward. In the absence of such mechanisms, care should be extended to follow the order specified by the documentation for all extension content.

Note that XML is case sensitive, and case sensitivity plays a role in creating a valid CTR-XML file. For example, ItemGroupOID="DM" is not the same as ItemGroupOID="dm".

4 General Specifications for CTR-XML

4.1 Structure of the CTR-XML

This document describes how a set of extensions to the CDISC ODM Standard Version 1.3.2 and to the SDM-XML (Study Design Model in XML) Standard v.1.0, can be used to provide study definition / study design information to clinical trial registries (CTRs) such as the WHO ICRTP, EudraCT, or ClinicalTrials.gov.

While there is considerable overlap in the requirements for submissions to each of these registries, the CTR-XML required to register any given study in all three registries will not be identical. The WHO registry has defined a set of 20 core required elements, known as the TRDS. The goal in developing this standard is to provide a standard for representing the 20 TRDS requirements that can be re-used for submissions to ClinicalTrials.gov and to the EudraCT registry.

Section 4.2 describes how to represent the 20 WHO TRDS information requirements and discusses how these elements map to required elements in ClinicalTrials.gov and EudraCT. It provides examples in the text for the WHO registry case.

Section 4.3 describes information requirements for submissions to the ClinicalTrials.gov and EudraCT registries that go beyond the WHO TRDS and describes how to represent this additional information using CTR-XML.

CTR-XML uses elements and attributes from four namespaces. The following principles were applied in deciding which namespaces to use for each piece of information to be submitted:

- CTR information elements that are part of the ODM are used as is.
- CTR information elements that are part of SDM-XML are used as is. In a few cases where a SDM-XML element is conceptually the same as a CTR element but is missing a sub-component, the SDM-XML element has been extended.
- CTR information elements that are not part of the ODM or SDM-XML, but are defined in the EudraCT XML schemas, are used without extensions.
- CTR information elements that are not part of the ODM, SDM-XML or the EudraCT XML schemas are defined as part of the CTR-XML extension.

Section 5 provides detailed technical requirements for the set of information elements that may appear within CTR-XML documents.

Appendix B: Trial Summary Parameters that Need to be Included for Submission to a Clinical Trial Registry provides a list of trial parameters that must be submitted in sdm:Parameter elements within the sdm:Summary section of the CTR-XML. Many of these parameters are subject to CDISC Controlled Terminology.

4.2 WHO TRDS Requirements

This part of the document is organized by the WHO TRDS requirements. For each requirement, the corresponding concepts used by ClinicalTrials.gov and EudraCT are identified and XML examples are provided to show how to combine the XML elements for submission of this information.

4.2.1 TRDS-1 to TRDS-3: Primary Registry and Trial Identifying Number / Date of Registration in Primary Registry / Secondary Identifying Numbers

WHO	Primary Registry and Trial Identifying Number, Date of Registration in Primary Registry, Secondary Identifying Numbers
EudraCT	EudraCT number, Secondary ID, Secondary ID Type, Secondary ID Issuing Organization
ClinicalTrials.gov	ClinicalTrials.gov NCT number, Study Start Date

TRDS-1 is the Primary Registry and Trial Identifying Number
TRDS-2 is the Date of Registration in Primary Registry
TRDS-3 is the Secondary Identification Numbers.

The CTR-XML extension provides a *Registrations* container element that may contain one or more *Registration* child elements – one for each Registration element containing the details of a single registration. In Example 4.2.1.1, there is a *ctr:Registration* element with information about the Primary Registration Authority, ClinicalTrials.gov, and another *ctr:Registration* with information about the Secondary Authority.

4.2.1.1 Example Identifying Information

```
<ctr:Registrations>
   <ctr:Registration Type="Primary" RegistrationDate="2015-05-26"
        RegistrationAuthority="ClinicalTrials.gov" RegistrationID="NCT02467127"/>
   <ctr:Registration Type="Secondary" RegistrationAuthority="University of
        Cantanzaro" RegistrationID="Headache 2015"/>
</ctr:Registrations>
```

The *ctr:Registrations* element is a container element that comes under the ODM *GlobalVariables* and contains at least 1 *ctr:Registration* element.

The *Type* attribute value "Other" may be used for other registration IDs such as those issued by funding bodies, collaborative research groups, regulatory authorities, ethics committees or institutional review boards.

When the *RegistrationID* is used for the (WHO) "Universal Trial Number" (UTN), the value of the Type attribute must be "Universal".

Note that the values for the *RegistrationAuthority* attribute may be subject to CDISC Controlled Terminology.

4.2.2 TRDS-4 to TRDS-6: Source(s) of Monetary or Material Support / Primary Sponsor / Secondary Sponsor(s)

WHO	Sources of Monetary or Material Support, Primary Support, Secondary Sponsor(s)
EudraCT	Sponsor/ monetary_supports
ClinicalTrials.gov	Sponsors/Collaborators (lead_sponsor)

TRDS-4 is the Source(s) of Monetary or Material Support
TRDS-5 is the Primary Sponsor
TRDS-6 is the Secondary Sponsor

For the WHO ICTRP, there can be only one primary sponsor but there may be any number of secondary sponsors. The attribute *SponsorType* is used to distinguish between a primary and secondary sponsor. For EudraCT there is no distinction between primary and secondary sponsors or sources of monetary support.

The CTR-XML elements that are needed to represent the information required for TRDS-4, TRDS-5 and TRDS-6 are illustrated in Example 4.2.2.1. The element *ctr:FundingSupport* serves as a container element for the *ctr:Sponsor* element that references a *ctr:Organization* element that contains details about the sponsoring organization. The *ctr:Organization* element is a child element of the ODM AdminData element.

4.2.2.1 Example Monetary or Material Support

```
<Study OID="2A2-MC-EFGH" ctr:ResponsiblePartyType="PrincipalInvestigator">
   <GlobalVariables>
      …
      <ctr:FundingSupport>
         <ctr:Sponsor SponsorType="Primary" OrganizationOID="ORG.1"/>
      </ctr:FundingSupport>
   </GlobalVariables>
</Study>
…
<AdminData>
   <User OID="U.1" UserType="Investigator">
      <FullName>Luca Gallelli, MD</FullName>
      <Email>Gallelli@unicz.it</Email>
      <ctr:Role Context="ClinicalTrials.Gov">Primary Investigator</ctr:Role>
   </User>
   <ctr:Organization OID="ORG.1" Name="University of Cantanzaro"/>
</AdminData>
```

In cases where the trial sponsor is an individual rather than an organization, a *User* element within an *AdminData* element will be referenced in the *ctr:Sponsor* element in place of *ctr:Organization*. See Section 5.3.3.9.1 for the detailed specification of the ctr:Sponsor element.

Business Rules:

- EudraCT does not make a distinction between primary and secondary sponsors or sources of monetary support so the *SponsorType* attribute does not need to be provided in CTR-XML documents intended for use in a EudraCT submission.
- The attribute *SponsorType* should appear either on all *Sponsor* elements within *ctr:FundingSupport* or on none of them.
- Within the element *ctr:FundingSupport*, only one child element *Sponsor* can have the *SponsorType* attribute with the value "Primary".

Note that EudraCT requires the name of the supporting organization and the country of the financial support. Users will need to take care that this name and country information is provided through the *AdminData ctr:Organization* Element or through the *AdminData User* Element.

For ClinicalTrials.gov submissions, Collaborators are identified with the value "Secondary" for the *SponsorType* attribute.

4.2.3 TRDS-7 to TRDS-8: Contact for Public / Scientific Queries

WHO	Contact for Public Queries, contact for Scientific Queries
EudraCT	Sponsor Contact (Section B of Protocol Spreadsheet).
ClinicalTrials.gov	Recruitment Information/Contacts/Contact

In CTR-XML the *ctr:Contacts* and *ctr:Contact* elements are used to transmit all contact information for the primary contact, the contact for scientific queries (WHO), and the contact for public queries (WHO).

The *UserOID* attribute in the *ctr:Contact* element references a *User* element within the *AdminData* and the *ContactRoleCodeListOID* references a *Codelist* within the *MetaDataVersion* element. An ODM *Codelist* must be provided within the CTR-XML file to provide the list of Contact Roles.

4.2.3.1 Example ctr:Contacts Usage

```
<GlobalVariables>
   …
   <ctr:Contacts>
      <ctr:Contact UserOID="U.1" ContactRole="PRIMARY CONTACT"
            ContactRoleCodeListOID="CL.CONTACTROLES"/>
      <ctr:Contact UserOID="U.1" ContactRole="CONTACT FOR SCIENTIFIC QUERIES"
            ContactRoleCodeListOID="CL.CONTACTROLES"/>
      <ctr:Contact UserOID="U.1" ContactRole="CONTACT FOR PUBLIC QUERIES"
            ContactRoleCodeListOID="CL.CONTACTROLES"/>
   </ctr:Contacts>
</GlobalVariables>
```

The allowable values for the *ContactRole* attribute will be defined with an extensible CDISC Controlled Terminology. The provisional list of values is given below.

Provisional Controlled Terminology for Clinical Trial Registry *ContactRole*:

Term	Explanation / Remarks
PRIMARY CONTACT	
CONTACT FOR PUBLIC QUERIES	
CONTACT FOR SCIENTIFIC QUERIES	
CA APPLICANT	Required by EudraCT
LEGAL REPRESENTATIVE	Required by EudraCT in case the sponsor is not established in the European Economic Area (EEA)
IEC APPLICANT	Optional field in EudraCT
PRINCIPAL INVESTIGATOR	
INVESTIGATOR	
FACILITY CONTACT	EudraCT
FACILITY CONTACT BACKUP	EudraCT
NETWORK CONTACT	EudraCT
SUBCONTRACTOR CONTACT	EudraCT
FURTHER CONTACT INFORMATION	EudraCT
CENTRAL CONTACT	ClinicalTrials.gov
CENTRAL CONTACT BACKUP	ClinicalTrials.gov
STUDY CHAIR	ClinicalTrials.gov
STUDY DIRECTOR	ClinicalTrials.gov

4.2.4 TRDS-9 Public Title

WHO	Public Title
EudraCT	Full Title, Lay Person Title, Abbreviated Title
ClinicalTrials.gov	Brief Title (protocol title intended for the lay public)

The Public Title is the title for the general public. It is meant to be written in language that is easily understood.

In consideration of the fact that this information is important and highly visible, the CTR-XML allows for translations. The ODM TranslatedText element is well suited to provide this functionality as shown in Example 4.2.4.1.

4.2.4.1 Example Public Title

```
<ctr:PublicTitle>
   <TranslatedText xml:lang="en">
      Vitamin D Plasma Level and Its Role in Headache
   </TranslatedText>
   <TranslatedText xml:lang="de">
      Vitamin D Plasma Niveau und ihre Rolle in Kopfschmerzen
   </TranslatedText>
</ctr:PublicTitle>
```

Note that the use of multiple languages for *PublicTitle* is NOT a WHO requirement: only the English title is required.

4.2.5 TRDS-10 Scientific Title

WHO	Scientific Title
EudraCT	Full Title
ClinicalTrials.gov	Official Title

The scientific title will usually be taken from the study protocol document. The ODM *StudyName* element in the ODM Study GlobalVariables element is used for this information as shown in Example 4.2.5.1.

The use of multiple languages for Scientific Title is NOT a WHO requirement, only the English title needs to be provided. An extended child element *ctr:StudyNameLocalizations* is provided to be used in cases where the scientific title must be localized. When two or more localizations of the study Scientific Title are required, the *ctr:StudyNameLocalizations* element will contain a *TranslatedText* element for each locale.

4.2.5.1 Example Scientific Title

```
<GlobalVariables>
   <StudyName>
      The Role of Vitamin D Plasma Levels in the Development of Headache
   </StudyName>
   …
</GlobalVariables>
```

4.2.6 TRDS-11: Countries of Recruitment

WHO	Countries of Recruitment
EudraCT	Planned_region
ClinicalTrials.gov	Location_countries

In the CTR-XML, countries of recruitment are defined within the *ctr:Recruitment* element using the *ctr:RecruitmentCountries* child element. For each country there will be a *ctr:RecruitmentCountry* element with a reference to a country CodeList that is provided within the CTR-XML file. The WHO recommends the use of ISO country codes such as ISO 3166-1 alpha 3. When implementing this recommendation a *Codelist* with an *ExternalCodelist* child element must be provided in the CTR-XML file. If the user prefers, it is also possible to provide a codelist with just the countries where recruiting is planned.

4.2.6.1 Example Recruitment Countries

```
<CodeList OID="CL.ISOCountries" Name="Country Codes" DataType="text">
   <ExternalCodeList Dictionary="ISO 3166 alpha-3"/>
</CodeList>
<ctr:Recruitment>
   <ctr:RecruitmentCountries>
      <ctr:RecruitmentCountry CountryCode="USA" CodeListOID="CL.ISOCountries"/>
   </ctr:RecruitmentCountries>
   <ctr:RecruitmentStatus CurrentStatus="Recruiting"
         RecruitmentStartDate="2015-05-26"/>
</ctr:Recruitment>
```

4.2.7 TRDS-12: Health Condition(s) or Problem(s) Studied

WHO	Health condition(s) or problem(s) studied
EudraCT	Medical conditions
ClinicalTrials.gov	Conditions or Keywords (using NLM Medical Subject Heading (MeSH) terms)

The CDISC Controlled Terminology for the SDTM Trial Summary dataset includes the term INDIC to refer to trial indication so the WHO Health Condition(s) study information uses the SDM-XML *sdm:Parameter* with the ShortName="INDIC" to provide the information needed for the Health Condition(s) field in the WHO registry.

4.2.7.1 Example INDIC Parameter

```
<Protocol>
   …
   <sdm:Summary>
      <sdm:Parameter OID="PAR.INDIC" ShortName="INDIC" Term="Trial Indication">
         <sdm:Value>Headache</sdm:Value>
      </sdm:Parameter>
   </sdm:Summary>
   …
</Protocol>
```

For ClinicalTrials.gov, the National Library of Medicine's Medical Subject Headings (MeSH) may be used. The browser version of MeSH is available at https://www.nlm.nih.gov/mesh/MBrowser.html and a downloadable copy in XML format is available at https://www.nlm.nih.gov/mesh/filelist.html. When an external codelist such as MeSH is used as the source of terms for the INDIC parameter, an extended attribute *ctr:CodeListOID* is added to the *sdm:Value* element as shown. For other registries, the use of other terminology standards, such as SNOMED, may be preferred.

4.2.7.2 Example INDIC Parameter with Controlled Terminology

```
<sdm:Parameter OID="PAR.INDIC" ShortName="INDIC" Term="Trial Indication">
   <sdm:Value ctr:CodeListOID="CL.NLMESH">Headache</Value>
</sdm:Parameter>
…
<CodeList OID="CL.MeSH" Name="MeSH CT">
   <ExternalCodeList Dictionary="National Library of Medicine MeSH"
         Version="July 2015 International Version"
         href="http://www.nlm.nih.gov/mesh/MBrowser.html"/>
</CodeList>
```

Note that only ODM External Codelists are allowed to be used in this context.

When a controlled terminology source that uses codes for conditions, such as SNOMED-CT, LOINC, or ICD-10 is used the *sdm:Value* will contain the coded value, and the ctr:*DisplayValue* attribute will be used to provide the text decode.

4.2.7.3 Example INDIC Using Codes and Decodes with Controlled Terminology

```
<sdm:Parameter OID="PAR.INDIC" ShortName="INDIC" Term="Trial indications">
   <sdm:Value ctr:CodeListOID="CL.SNOMEDCT"
         ctr:DisplayValue="Alzheimer's Disease">26929004</sdm:Value>
</sdm:Parameter>
```

EudraCT requires the submission of the therapeutic area for the disease under study in addition to the condition. The THERAREA parameter should be used to provide the therapeutic area as example 4.2.7.4 illustrates.

4.2.7.4 Example INDIC Adding Therapeutic Area for EudraCT

```
<Protocol>
   …
   <sdm:Summary>
      <sdm:Parameter OID="PAR.INDIC" ShortName="INDIC" Term="Trial Indication">
         <sdm:Value>Headache</sdm:Value>
      </sdm:Parameter>
      <sdm:Parameter OID="PAR.THERAREA" ShortName="THERAREA"
            Term="Therapeutic Area">
         <sdm:Value>Neurology</Value>
      </sdm:Parameter>
   </sdm:Summary>
   …
</Protocol>
```

If the medical condition needs to be provided in several languages, the child element *TranslatedText* may be used as illustrated in Example 4.2.7.5.

4.2.7.5 Example INDIC with Translated Text

```
<sdm:Summary>
   <sdm:Parameter OID="PAR.INDIC" ShortName="INDIC" Term="Trial Indication">
      <sdm:Value>
         <TranslatedText xml:lang="en">Headache</TranslatedText>
      </sdm:Value>
      <sdm:Value>
         <TranslatedText xml:lang="de">Kopfschmerzen</TranslatedText>
      </sdm:Value>
      …
   </sdm:Parameter>
</sdm:Summary>
```

4.2.8 TRDS-13: Interventions

WHO	Intervention Name and Intervention Description by arm
EudraCT	medicinal_product_information / medicinal_product
ClinicalTrials.gov	Intervention Description / Intervention Name

The WHO minimum requirement for intervention(s) is to record a brief intervention name and a description for each arm of the trial. Provision is made for drugs where a generic name is available, investigational new drugs, and for non-drug intervention types. The description must be sufficiently detailed to enable registry users to distinguish between the arms of a study. For studies where there is a control arm, the identity of the control must be clear.

The CDISC *sdm:Arm* element is used to identify the study arm. As shown in the following example, each arm can be associated with an intervention by using the *ctr:InterventionOID* extended attribute to reference a *ctr:Intervention* element containing the required Intervention information.

4.2.8.1 Example Interventions by Study Arm

```
<MetaDataVersion>
   …
   <Protocol>
      …
      <sdm:Structure>
         <sdm:Arm OID="ARM.Intervention.1" Name="Treatment"
               ctr:InterventionOID="INT.VITAMIND"/>
         <sdm:Arm OID="ARM.Intervention.2" Name="Placebo"
               ctr:InterventionOID="INT.PLACEBO"/>
      </sdm:Structure>
   </Protocol>
   …
   <ctr:Interventions>
      <ctr:Intervention OID=" INT.VITAMIND" InterventionType="Dietary Supplement"
            Name="Vitamin D">
         <Description>
            <TranslatedText>vitamin D supplementation</TranslatedText>
         </Description>
      </ctr:Intervention>
      <ctr:Intervention OID="INT.PLACEBO" InterventionType="Other"
            Name="no treatment"/>
   </ctr:Interventions>
</MetaDataVersion>
```

The allowable values for the *InterventionType* attribute are defined in the CDISC SDTM Controlled Terminology "Intervention Type" (INTTYPE - NCI code C99078)[1].

Also note that there can be more than one *ctr:Intervention* element in a study, as different interventions can be compared in the study.

For crossover studies, two additional SDM-XML elements *sdm:Epoch* and *sdm:CellDef* are used to provide the intervention details for each arm as shown in Example 4.2.8.2.

[1] Note that the CDISC Controlled Terminology terms for "INTTYPE" (NCI code C990787) are in uppercase. This means that when generating SDTM datasets from CTR files, the values still need to be transformed to uppercase.

4.2.8.2 Example Intervention for Crossover Study

```
<sdm:Epoch Name="Treatment 1" OID="EPOCH.TX1">
   <Description>
      <TranslatedText xml:lang="en">First Treatment</TranslatedText>
   </Description>
</sdm:Epoch>
<sdm:Epoch Name="Treatment 2" OID="EPOCH.TX2">
   <Description>
      <TranslatedText xml:lang="en">Second Treatment</TranslatedText>
   </Description>
</sdm:Epoch>
<sdm:Arm Name="Low dose arm" OID="ARM.LOWDOSE"
      ctr:InterventionOID="INT.Xanomelin_Low">
   <Description>
      <TranslatedText xml:lang="en">Low-dose arm: 50 cm2 TTS Formulation E, 54 mg
         xanomeline</TranslatedText>
   </Description>
</sdm:Arm>
<sdm:Arm Name="High dose arm" OID="ARM.HIGHDOSE"
      ctr:InterventionOID="INT.Xanomelin_High">
   <Description>
      <TranslatedText xml:lang="en">High-dose arm: 75 cm2 TTS Formulation E, 81 mg
         xanomeline</TranslatedText>
   </Description>
</sdm:Arm>
<sdm:CellDef EpochOID="EP.EPOC.TX1" Name="TX1 Low" OID="CELL.TX1.Low">
   <sdm:ArmAssociation Type="Blinded">
      <sdm:ArmRef ArmOID="ARM.PLACEBO"/>
      <sdm:ArmRef ArmOID="ARM.LOWDOSE" ctr:InterventionOID="INT.Xanomelin_Low"/>
      <sdm:ArmRef ArmOID="ARM.HIGHDOSE" ctr:InterventionOID="INT.Xanomelin_High"/>
   </sdm:ArmAssociation>
   <sdm:SegmentRef OrderNumber="1" SegmentOID="SEG.TREATMENT1"/>
</sdm:CellDef>
```

ClinicalTrials.gov requires additional information describing the category to which each arm belongs (ClinicalTrials.gov Section 8). The enumerated types are:

- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No intervention
- Other

4.2.9 TRDS-14: Key Inclusion and Exclusion Criteria

WHO	Key Inclusion and Exclusion Criteria
EudraCT	Principal Inclusion Criteria, Principle Exclusion Criteria
ClinicalTrials.gov	Eligibility Criteria

The CDISC SDM-XML model provides the *sdm:InclusionExclusionCriteria* element as a container for *sdm:InclusionCriteria* and *sdm:ExclusionCriteria* elements. Both *sdm:InclusionCriteria* and *sdm:ExclusionCriteria* contain one or more *sdm:Criterion* elements. Each *sdm:Criterion* element references an ODM *ConditionDef* element which provides a description of the criteria.

4.2.9.1 Example Inclusion and Exclusion Criteria

```
<MetaDataVersion OID="E2B7891D-BA2C-4F69-AF82-020B855A6D3E" Name="2A2-MC-EFGH-C1" >
   <Protocol>
      <sdm:InclusionExclusionCriteria>
         <sdm:InclusionCriteria>
            <sdm:Criterion OID="INCL.01" ConditionOID="COND.INCL1"
                  Name="Acute or chronic headache"/>
         </sdm:InclusionCriteria>
         <sdm:ExclusionCriteria>
            <sdm:Criterion OID="EXCL.01" ConditionOID="COND.EXCL1"
                  Name="Drug allergy"/>
            <sdm:Criterion OID="EXCL.02" ConditionOID="COND.EXCL2"
                  Name="Serious medical condition"/>
            …
         </sdm:ExclusionCriteria>
      </sdm:InclusionExclusionCriteria>
   </Protocol>
   …
   <ConditionDef OID="COND.INCL1" Name="Inclusion 01">
      <Description>
         <TranslatedText>acute or chronic headache diagnosed according to the
               clinical and radiological criteria of the headache
               association</TranslatedText>
      </Description>
   </ConditionDef>
   <ConditionDef OID="COND.EXCL1" Name="Exclusion 01">
      <Description>
         <TranslatedText>allergy to drugs</TranslatedText>
      </Description>
   </ConditionDef>
   <ConditionDef OID="COND.EXCL2" Name="Exclusion 02">
      <Description>
         <TranslatedText>progressive serious medical conditions (such as cancer,
               AIDS or end stage renal disease)</TranslatedText>
      </Description>
   </ConditionDef>
```

4.2.10 TRDS-15: Study Type

WHO	Study Type ("Interventional" or "Observational")
EudraCT	Trial Type
ClinicalTrials.gov	Study Type "Interventional", "Observational", "Expanded Access" (component of Study Identification)

WHO and ClinicalTrials.gov differ in how the designation Interventional or Observational is considered and used, but in both cases the *sdm:Parameter* element named "StudyType" is used to provide this information. For ClinicalTrials.gov, the Study Type is part of the high-level Study Identification – and the parameter can also take the value "Expanded Access". For submissions to EudraCT, the Study Type parameter is not required.

The *sdm:Parameter* element with *Name* "STYPE" is used to represent the Study Type or Trial Type data. Note that the allowable values that are represented in the *sdm:Value* child element differ by registration authority. The applicable Controlled Vocabulary shall be provided using a *CodeList* element and the *sdm:Value* child element must provide the Codelist OID in the *ctr:CodeListOID* attribute.

4.2.10.1 Example Study Type

```
<sdm:Summary>
   …
   <sdm:Parameter OID="PAR.STYPE" ShortName="STYPE" Term="StudyType">
      <sdm:Value ctr:CodeListOID="CL.C99077.STYPE">INTERVENTIONAL</sdm:Value>
   </sdm:Parameter>
   …
</sdm:Summary>
```

The WHO document "International Standards for Clinical Trial Registries" describes Study Type as *"… a multi-dimensional concept, and registers may or may not collect each dimension and, if they do so, collect them in different formats. Our suggestion is that study design be split into type of study, study design, and phase. Study design is itself a multi-dimensional concept so it has itself been split into allocation, masking, control, assignment, and purpose. These sub-items are based on existing terms used by ClinicalTrials.gov."*

In CTR-XML, Allocation, Assignment and Purpose information are represented using the following CDISC Trial Summary parameters:

WHO	CDISC Trial Summary Parameter Name	CDISC Trial Summary Display Name
Allocation	RANDOM	Trial is Randomized
Assignment	INTMODEL	Intervention Model
Purpose	OBJPRIM	Primary Objective

4.2.10.2 Example of Study Type Allocation, Intervention Model and Primary Objective

```
<sdm:Summary>
   …
   <sdm:Parameter OID="PAR.RANDOM" Name="RANDOM" Term="Trial is randomized">
      <sdm:Value>Y</sdm:Value>
   </sdm:Parameter>
   <sdm:Parameter OID="PAR.INTMODEL" Name="INTMODEL" Term="Intervention Model">
      <sdm:Value>PARALLEL</sdm:Value>
   </sdm:Parameter>
   <sdm:Parameter OID="PAR.OBJPRIM" Name="OBJPRIM" Term="Primary Objective">
      <sdm:Value>Treatment</sdm:Value>
   </sdm:Parameter>
   …
</sdm:Summary
```

Each study arm shall be described in CTR-XML using the *Arm* element from the SDM-XML namespace. In SDM-XML the definitions of arms, epochs and cells are:

- *sdm:Arm*: OID, Name and localized (multi-language) description of each arm in the study
- *sdm:Epoch*: OID, Name, OrderNumber and localized (multi-language) description of each epoch (period) in the study
- *sdm:CellDef*: A cell is the intersection of an epoch with an arm

When there is more than one arm, the value for the WHO Assignment field will be supplied by a *sdm:Parameter* where the *sdm:Value* child element follows the CDISC Controlled Terminology INTMODEL, NCI code C99076:

- CROSS-OVER
- FACTORIAL
- PARALLEL
- SINGLE GROUP

The masking or blinding information is provided using the *sdm:CellDef* element in SDM-XML. The attribute *Type* on the element *sdm:ArmAssociation* can have the following values:

- Blinded
- Unblinded

An extended child element *ctr:BlindedRole* is added to the *sdm:CellDef* element. The text content of *ctr:BlindedRole* can have the values:

- Subject
- Investigator
- Monitor
- Data analyst
- Care provider
- Assessor

4.2.10.3 Example of Study Type Masking Status

```
<sdm:CellDef OID="TRECELL" Name="Treatment Cell" EpochOID="TREPOCH">
   <Description>
      <TranslatedText xml:lang="en">Treatment cell</TranslatedText>
   </Description>
   <sdm:ArmAssociation Type="Blinded">
   <!-- list of arms to which this cell is applicable -->
      <sdm:ArmRef ArmOID="PLACEBO_ARM"/>
      <sdm:ArmRef ArmOID="LOWDOSE_ARM"/>
      <sdm:ArmRef ArmOID="HIGHDOSE_ARM"/>
      <ctr:BlindedRole>Subject</ctr:BlindedRole>
      <ctr:BlindedRole>Investigator</ctr:BlindedRole>
   </sdm:ArmAssociation>
</sdm:CellDef>
```

The controlled terminology requirements for Study or Trial Phase vary across the three registration authorities.

EudraCT has the following enumerated values:

- Human Pharmacology (Phase I)
- Therapeutic Exploratory (Phase II)
- Therapeutic Confirmatory (Phase III)
- Therapeutic Use (Phase IV)

Note EudraCT does not require registration of Phase 1 trials.

ClinicalTrials.gov has the following enumerated values with a short explanation/meaning in parentheses:

- N/A (not applicable)
- Phase 0 (exploratory trials)
- Phase 1
- Phase 1/Phase 2 (for trials that are a combination of Phases 1 and 2)
- Phase 2
- Phase 2/Phase 3 (for trials that are a combination of Phases 2 and 3)
- Phase 3
- Phase 4 (studies of FDA-approved drugs)

CDISC Controlled Terminology has the following enumerated values for trial summary parameter TPHASE (TSPARMCD=TPHASE), NCI code C66737:

- NOT APPLICABLE
- Phase I Trial
- Phase I/II Trial
- Phase II Trial
- Phase II/III Trial

- Phase IIa Trial
- Phase IIb Trial
- Phase III Trial
- Phase IIIa Trial
- Phase IIIb Trial
- Phase IV Trial
- Phase V Trial

To identify which definition of Phase applies, a *ctr:Scope* extended attribute on the *sdm:Value* element is used.

4.2.10.4 Example of Study Phase

```
<sdm:Parameter OID="IT.TPHASE" ShortName="TPHASE" Term="Trial Phase">
   <sdm:Value>Phase IIb Trial</sdm:Value>
   <sdm:Value ctr:Scope="EudraCT">Therapeutic Exploratory (Phase II)</sdm:Value>
   <sdm:Value ctr:Scope="ClinicalTrials.gov">Phase 2</sdm:Value>
</sdm:Parameter>
```

4.2.11 TRDS-16: Date of First Enrollment

WHO	Anticipated or Actual date of enrollment of first participant.
EudraCT	Study Start Date, Study End Date
ClinicalTrials.gov	Study Start Date, Study End Date

The *ctr:StudyStartDate* element and *ctr:StudyEndDate* elements are used to provide the Study Start Date and Study End Date information required for WHO, EudraCT and ClinicalTrials.gov. The *Type* attribute on the *ctr:StudyStartDate* element is used to indicate whether the date supplied is an "Actual" or "Anticipated" date.

Business Rule: Use of partialDates is permitted when an anticipated date is provided. When providing an actual date a complete date is required.

4.2.11.1 Example Date of First Enrollment

```
<ctr:StudyStartDate Type="Anticipated">2015-04</ctr:StudyStartDate>
```

For submissions to EudraCT and ClinicalTrials.gov where the study end date is required, the *ctr:StudyEndDate* is used to contain this information.

Note that the values of the ctr:StudyEndDate Type attribute are mapped to the EudraCT "Global end of trial reached? Yes/No" field as shown:

CTR-XML	***EudraCT: Global end of trial reached?***
Type="Anticipated"	*No*
Type="Actual"	*Yes*

For ClinicalTrials.gov "Primary Completion Date", see section ClinicalTrials.gov Specific Elements

4.2.12 TRDS-17: Target Sample Size

WHO	Planned number of participants to be enrolled
EudraCT	Population Planned numbers in member state and in EEA in trial as whole
ClinicalTrials.gov	Study Design/Enrollment

The *sdm:Parameter* element with *ShortName*="PLANSUB" (and *DisplayName*="Planned number of subjects") is used to provide this information for WHO and for EudDRACT. This is covered by the CDISC trial summary parameter "PLANSUB", NCI code C49692, in SDM-XML.

4.2.12.1 Example of Planned Number of Participants

```
<sdm:Parameter OID="PAR.PLANSUB" ShortName="PLANSUB"
      Term="Planned Number of Subjects">
   <sdm:Value>1200</sdm:Value>
</sdm:Parameter>
```

EudraCT requires much more detailed information about planned number of subjects, such as per age range, inside and outside the member state, EEA, etc. (Sections F.1 to F.4 in the 2009 guidelines). The EudraCT XML element *ct:population_information* defined in the EudraCT namespace http://eudract.emea.europa.eu/schema/clinical_trial may be used within a CTR-XML document.

4.2.12.2 Example of Planned Participants Details Using EMA ct: Extension

```
<MetaDataVersion OID="E2B7891D-BA2C-4F69-AF82-020B855A6D3E"
      Name="2A2-MC-EFGH-C1" >
…
<ctr:StudyEndDate>
   <ct:population_information
         xmlns:ct="http://eudract.emea.europa.eu/schema/clinical_trial">
      <ct:has_under_18>0</ct:has_under_18>
      <ct:has_healthy_volunteers>1</ct:has_healthy_volunteers>
      <!-- other EudraCT-specific population elements -->
      <!-- detailed EudraCT-specific info on planned nbr of subjects -->
      <!-- Population planned numbers in EU member states -->
      <ct:in_ms_no>367</ct:in_ms_no>
      <!-- Population planned numbers in European Economic Area -->
      <ct:in_eea_no>512</ct:in_eea_no>
      <!-- Population planned numbers in whole trial -->
      <ct:in_whole_trial>1088</ct_in_whole_trial>
   </ct:population_information>
</ctr:StudyEndDate>
```

4.2.13 TRDS-18: Recruitment Status

WHO	Recruitment status of this trial (*Pending*, *Recruiting*, *Suspended*, *Complete*, *Other)* per country or worldwide
EudraCT	Not required
ClinicalTrials.gov	Study Status/Overall Recruitment Status ("Not yet recruiting", "Recruiting", "Enrolling by invitation", "Active, not recruiting", "Completed", "Suspended", "Terminate", "Withdrawn")

The *ctr:RecruitmentStatus* element, a child element of the *ctr:Recruitment* element is used to transmit the recruitment status information. The *ctr:RecruitmentStatus* has a *Country* attribute. Omitting the Country attribute indicates that the Recruitment Status applies on a worldwide basis – that is in each planned country.

4.2.13.1 Example of Recruitment Status

```
<ctr:Recruitment>
   <ctr:RecruitmentStatus CurrentStatus="Recruiting"/>
</ctr:Recruitment>
```

Since no Country attribute is specified, the study is recruiting worldwide.

Business Rules:

- There may only be one *ctr:RecruitmentStatus* element without *Country* attribute.
- The value of the *Country* attribute must be unique within its series of *ctr:RecruitmentStatus* elements, i.e. there may not be two *ctr:Recruitment* elements with the same value of the *Country* attribute.
- The value of *RecruitmentStartDate* may not be later than the value of *RecruitmentEndDate.*
- The child element *ctr:RecruitmentStatusOther* may only be present when the value of the *CurrentStatus* attribute on the parent *ctr:RecruitmentStatus* element is "Other".

4.2.13.2 Example of Country Specific Recruitment Status

```
<ctr:Recruitment>
   <ctr:RecruitmentStatus Country="USA" CurrentStatus="Pending"
         RecruitmentStartDate="2015-02-17" RecruitmentEndDate="2016-01-01"/>
   <ctr:RecruitmentStatus Country="GER" CurrentStatus="Recruiting"
         RecruitmentStartDate="2015-01-01" RecruitmentEndDate="2016-01-01"/>
   <ctr:RecruitmentStatus Country="FRA" CurrentStatus="Pending"
         RecruitmentStartDate="2015-05-01" RecruitmentEndDate="2016-01-01"/>
</ctr:Recruitment>
```

When the value of the *CurrentStatus* attribute is "Other", the *ctr:RecruitmentStatusOther* element provides the details.

4.2.13.3 Example of Recruitment Status "Other"

```
<ctr:RecruitmentStatus Country="CAN" CurrentStatus="Other">
   <ctr:RecruitmentStatusOther>
      IE criteria are in development
   </ctr:RecruitmentStatusOther>
</ctr:RecruitmentStatus>
```

4.2.14 TRDS-19 and TRDS-20: Primary Outcome(s) and Secondary Outcome(s)

WHO	Name of the outcome, metric of method of measurement, timepoint(s) of interest
EudraCT	Primary Endpoint, Endpoint Timepoint
ClinicalTrials.gov	Primary Outcome Measures

Most trials should have only one primary outcome. There is no limit on the number of secondary outcomes. According to WHO, outcomes may be "… events, variables or experiences that are measured because it believed they may be influenced by the intervention".

Business Rules:

- The name of the outcome should be the full name of the outcome (no abbreviations).
- The metric or method of measurement should be as specific as possible.
- The timepoint(s) of primary interest should be provided.

In the CTR-XML, both the Primary and Secondary Outcome information is represented using the *ctr:OutcomeMeasures* and *ctr:OutcomeMeasure* elements as illustrated in the example below.

4.2.14.1 Example of Primary and Secondary Outcomes

```
<ctr:OutcomeMeasures>
   <ctr:OutcomeMeasure OID="OM.1" Name="Primary Outcome" Type="Primary">
      <Description>
         <TranslatedText>Plasma levels of vitamin D</TranslatedText>
      </Description>
      <ctr:TimePoint>
         <Description>
            <TranslatedText>up to 24 weeks</TranslatedText>
         </Description>
      </ctr:TimePoint>
   </ctr:OutcomeMeasure>
   <ctr:OutcomeMeasure OID="OM.2" Name="Secondary Outcome" Type="Secondary”>
      <Description>
         <TranslatedText>Headache</TranslatedText>
      </Description>
      <ctr:TimePoint>
         <Description>
            <TranslatedText>up to 24 weeks</TranslatedText>
         </Description>
      </ctr:TimePoint>
   </ctr:OutcomeMeasure>
</ctr:OutcomeMeasures>
```

The EudraCT Data dictionary includes two text fields for tracking information about the Primary (and secondary) Endpoint:

- Primary end points
- Endpoint timepoint

The ClinicalTrials.gov requirements for Primary and Secondary Outcome Measures are:

- Title
- Time Frame
- Description
- Safety Issue indicator

The *ctr:OutcomeMeasures* is a container element for 1 or more *ctr:OutcomeMeasure* elements.

The *ctr:OutcomeMeasure* element has an *OID* identifier attribute, a *Name* attribute (mandatory), and a *Type* attribute (mandatory). *Type* is enumerated to "Primary" for a primary outcome measure and "Secondary" for a secondary outcome measure.

The *ctr:OutcomeMeasure* element has an ODM *Description* child element that provides a detailed description of the outcome measure in different languages using 1 or more *TranslatedText* child elements.

The ClinicalTrials.gov element "other prespecified outcome measures" is covered by elements *ctr:OutcomeMeasure* for which the attribute *Type* has the value "Other".

The element *ctr:TimePoint* also has an ODM *FormalExpression* element which can be used for providing machine-readable/executable expressions about the time point.

4.2.14.2 Example of Primary Outcome with a TimePoint

```
<ctr:OutcomeMeasures>
   <ctr:OutcomeMeasure OID="MEAS.PRIM1" Name="Depression Outcome Measure"
         Type="Primary">
      <Description>
         <TranslatedText xml:lang="en">Here comes the extensive Description of the
               outcome measure</TranslatedText>
      </Description>
      <ctr:TimePoint>
         <Description>
            <TranslatedText xml:lang="en">10 days after start of follow-up
                  epoch</TranslatedText>
         </Description>
         <FormalExpression
               Context="XPath">//odm:Protocol/sdm:Structure/sdm:Epoch[@OID='FUPEPOCH']
               + P10D</FormalExpression>
      </ctr:TimePoint>
   </ctr:OutcomeMeasure>
</ctr:OutcomeMeasures>
```

The outcome measure in the above example describes a primary outcome of "depression" to be measured 10 days after the start of the follow-up epoch.

Note that *FormalExpression* has been added for future implementations, e.g. for systems that will provide an alert that an outcome has to be measured[2].

4.3 Minimal Requirements for Other Registration Authorities

This section describes elements that do not fall under the WHO minimal requirements but are part of the requirements for registration submissions to ClinicalTrials.gov and/or the EudraCT.

As has been previously noted, existing ODM elements and/or SDM-XML elements are used as much as possible and extended to capture additional information as needed.

4.3.1 Other Requirements Information

4.3.1.1 Sponsor Protocol Version and Date

Other required sponsor protocol version and date information include:

- EudraCT: Sponsor protocol code, Sponsor protocol version, Sponsor protocol version date, Sponsor protocol change date
- ClinicalTrials.gov: Organization's Unique Protocol Id

The ODM *Protocol* element under *MetaDataVersion* currently contains the child elements:

- *Description*: contains one or more free text descriptions in different languages
- *StudyEventRef*: a set of elements that reference *StudyEventDef* elements, which essentially are detailed visit descriptions
- *Alias*: zero or more elements that provide synonyms for other contexts

The *MetaDataVersion* element is primarily used for providing one or more versions of the metadata of the study.

The ODM *Protocol* element is extended with the following attributes:

- *ctr:ProtocolId*: mandatory attribute for the Sponsor/Organization's unique protocol ID
- *ctr:ProtocolVersion*: a conditionally mandatory attribute in CTR-XML for the Sponsor protocol version

[2] Essentially, an outcome measure is an activity, which is also described by sdm:Activity in SDM-XML. So in future, we may allow an activity to be referenced from the *ctr:OutcomeMeasure* element.

- *ctr:ProtocolVersionDate*: a conditionally mandatory CTR-XML attribute in ISO-8601 date format for the date of the current protocol version
- *ctr:ProtocolVersionChangeDate*: a conditionally mandatory CTR-XML attribute in ISO-8601 date format for the date of the last changed version of the sponsor's protocol

The attributes *ctr:ProtocolVersion* and *ctr:ProtocolVersionDate* are mandatory in the scope of an EurdraCT submission. The attribute *ctr:ProtocolVersionChangeDate* is mandatory in the scope of an EurdraCT submission when previous versions of the protocol have been published or submitted.

4.3.2 ClinicalTrials.gov Specific Elements

The elements / attributes described in this section are those that are required for ClinicalTrials.gov submissions but are not required for WHO or EudraCT registration submissions.

4.3.2.1 Study Design Parameters

Some of the ClinicalTrials.gov specific requirements are essentially key-value pairs that can be handled by Study Design Parameters, implemented as *sdm:Parameter* elements in SDM-XML. CTR-XML has used *sdm:Parameter* terms wherever possible, instead of new elements or attributes, since new terms can be added as needed by submitting requests to the CDISC Controlled Terminology Team.

The following pieces of information are covered by the following *sdm:Parameter* elements:

Parameter Short Name	Term	ClinicalTrials.gov element or section	Allowed values / comments
KEYWORD	Protocol Keyword*	Section 6 ClinicalTrials.gov	One parameter value for each individual keyword
STUDYCL	ClinicalTrials.gov Study Classification	ClinicalTrials.gov Section 7	N/A / Safety / Efficacy / Safety/Efficacy / Bio-equivalence / Bio-availability / Pharmacokinetics / Pharmacodynamics / Pharmacokinetics/dynamics
OBSMODEL*	Observational Model*	ClinicalTrials.gov Section 7	Cohort / Case-control / Case-only / Case-crossover / Ecologic or community studies / Family-based / Other
OBSTIMP*	Observational Time Perspective	ClinicalTrials.gov Section 7	Prospective / Retrospective / Cross-sectional / Other
BIOSPRET*	Biospecimen Retention Contains DNA	ClinicalTrials.gov Section 7	None Retained / Samples With DNA / Samples Without DNA
RTSPCDES*	Retained Biospecimen Description*	ClinicalTrials.gov Section 7	
TRGFUDUR*	Target Follow-Up Duration*	ClinicalTrials.gov Section 7	ISO-8601 "duration" format where only one of "Y", "M" or "D" may be used. For example P2Y, P24M, P730D
NCOHORT*	Number of Groups/Cohorts*	ClinicalTrials.gov Section 7	Non-negative integer
OBSTPOPD*	Observational Study Population Description*	ClinicalTrials.gov Section 10	
OBSTSMM*	Observational Study Sampling Method *	ClinicalTrials.gov Section 10	Probability Sample / Non-Probability Sample

OBSTSMMD*	Obs Study Sampling Method Description*	ClinicalTrials.gov Section 10	

Note that the controlled terminology for "Parameter Short Name" and "Term" **have not yet been approved by the CDISC Controlled Terminology Team.**

Business Rule:

- The parameters OBSMODEL, OBSTIMP, BIOSPRET, BIOSPDES, TRGFUDUR, NCOHORT, OBSTPOPD, OBSTSMM, and OBSTMMD are applicable only to observational studies and should not be used for submissions of interventional studies.

Note that "ClinicalTrials.gov Study Classification" includes some terms that are similar as well as some with different semantics with respect to "EudraCT Trial Scope".

4.3.2.2 Study Detailed Description

ClinicalTrials.gov requires a detailed description of the study which goes beyond "Title". The extended CTR-XML element *ctr:StudyDetailedDescription* shall be used to meet this requirement.

4.3.2.2.1 Example of a Detailed Study Description

```
<ctr:StudyDetailedDescription>
   <TranslatedText xml:lang="en">
      Several papers suggest that inflammation is able to induces both headache
      and low levels of vitamin D. However, to date a correlation between
      plasma vitamin D levels and headache has not been demonstrated. Recently
      we documented that low levels of Vitamin D are related to a low statin
      efficacy. In this study we will evaluate the plasma levels of vitamin D
      in patients with headache admitted to the Center of Headache of Pugliese
      Ciaccio Hospital.

      Moreover it will be also evaluated:
      *the correlation between efficacy and safety of drugs used in headache
      treatment and plasma vitamin D levels.
      *the role of vitamin D supplementation on both headache symptoms and drug
      effects.

      Plasma vitamin D levels in patients with headache will be evaluated
      respect to patients without headache.
   </TranslatedText>
</ctr:StudyDetailedDescription>
```

4.3.2.3 Primary Completion Date

ClinicalTrials.gov describes the "primary completion date" as "*the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome*". This date can be different from the "Study end date". The extended element *ctr:StudyEndDatePrimaryOutcome* shall be used to submit this information.

This element has the same structure as the element *ctr:StudyStartDate* and *ctr:StudyEndDate*, and comes after the element *ctr:StudyEndDate* under the *Study* element.

4.3.2.3.1 Example of the Primary Completion Date

```
<Study OID="LZZT" ctr:StudyType="Interventional"
      ctr:ResponsiblePartyType="Sponsor">
   …
   <ctr:StudyStartDate Type="Actual">2014-12-30</ctr:StudyStartDate>
   <ctr:StudyEndDate Type="Anticipated">2018-12</ctr:StudyEndDate>
   <!-- ClinicalTrials.gov specific elements -->
   <!-- Primary completion date -->
   <ctr:StudyEndDatePrimaryOutcome Type="Anticipated">
      2018-12
   </ctr:StudyEndDatePrimaryOutcome>
   …
</Study>
```

4.3.2.4 Responsible Party Type

The attribute *ctr:ResponsiblePartyType* on the element *Study* is required when a registration to ClinicalTrials.gov is envisaged. It is enumerated to "Sponsor", "Principal Investigator" and "Sponsor-Investigator".

Business Rules:

- If the attribute *ctr:ResponsiblePartyType*="Sponsor" then ClinicalTrials.gov requires a sponsor Organization (name).
- If the attribute *ctr:ResponsiblePartyType*="Principal Investigator" and "Sponsor-Investigator" the ClinicalTrials.gov requires a user name.

These are provided under the element *ctr:PrimarySponsor*.

4.3.2.4.1 Example of the Responsible Party Type

```
<Study OID="2A2-MC-EFGH" ctr:ResponsiblePartyType="Principal Investigator">
```

4.3.2.5 Study Oversight

For submissions to ClinicalTrials.gov, information about regulatory compliance must be provided including:

- FDA Regulated Intervention (Yes/No)
- Section 801 Clinical Trial (yes/No)
- Delayed Posting (Yes/No)
- Investigational New Drug (IND) Application:
    - IND/IDE Protocol
    - IND/IDE Grantor
    - IND/IDE Number
    - Has Expanded Access?
        - Expanded Access Record
- Human Subjects Review Board Approval
    - Board Approval Status
    - Board Approval Number
    - Board name
    - Board Affiliation
    - Board Contact
    - Data Monitory Committee
        - Country:Organization Name

The element *ctr:Authorities* is a container element for information about regulatory and oversight authorities. It comes under the ODM element *Study*, before the element *ct:medicinal_product_information* and after the element *ctr:StudyEndDatePrimaryOutcome*. It

contains optional elements *ctr:FDAInformation*, *ctr:InstitutionalReviewBoardEthicsCommittee,* and *ctr:OversightAuthority.*

The *ctr:FDAInformation* element contains the information required by ClinicalTrials.gov under "FDA Regulated Intervention". The *ctr:FDAInformation* element has the following attributes:

- *IsFDARegulatedIntervention*: a mandatory attribute enumerated to "Yes" or "No"
- *IsINDNDEProtocol*: a mandatory attribute enumerated to "Yes" or "No"
- *HasDataMonitoringCommittee*: an optional attribute enumerated to "Yes" or "No"

The *ctr:InstitutionalReviewBoardEthicsCommittee* element contains information about and status of a study in an institutional review board and ethics committee. It has an OID identifier attribute and an ApprovalStatus attribute with enumerated responses. This element contains the ctr:OrganizationRef and ctr:Contact child elements.

The *ctr:OversightAuthority* element contains information about national oversight authorities, including NCAs (National Competent Authorities) for which the registration applies. This element has mandatory *CountryCode*, *CodeListOID*, and *Name* attributes. It contains a *ctr:OrganizationRef* child element.

ISO-codes (e.g. ISO 3166-1 alpha-3) are preferred for *CountryCode*. In the following example, a code from a codelist, defined as an external codelist (i.e. an officially published codelist) is used.

4.3.2.5.1 Example of the Authorities for a Non-FDA Regulated Interventional Study

```
<ctr:Authorities >
   <ctr:FDAInformation IsFDARegulatedIntervention="No" IsINDNDEProtocol="No"
        HasDataMonitoringCommittee="No"/>
   <ctr:OversightAuthority CountryCode="ITA" CodeListOID="CL.Countries"
        Name="The Italian Medicines Agency">
      <ctr:OrganizationRef OrganizationOID="ORG.1"/>
   </ctr:OversightAuthority>
</ctr:Authorities>
```

A sponsor-specific country codelist or the CDISC-CT [COUNTRY] codelist can be used, with or without translations for the individual country codes. In this case the codelist will be defined and will include an EnumeratedItem or CodeListItem for each country in which the trial will be registered.

4.3.2.5.2 Example of the Authorities for an FDA Regulated Interventional Study

```
<ctr:Authorities>
   <!-- FDA information -->
   <ctr:FDAInformation IsFDARegulatedIntervention="Yes" IsINDNDEProtocol="Yes"
        HasDataMonitoringCommittee="No"/>
   <!-- Institutional Review Boards / Ethics Committees -->
   <ctr:InstitutionalReviewBoardEthicsCommittee OID="RB.REVIEWBOARD"
        Approval="Submitted, approved">
      <ctr:OrganizationRef OrganizationOID="ORG.REVIEWBOARD"/>
      <ctr:Contact UserOID="CONT.ANTHONY"
           ContactRoleCodeListOID="CL.CONTACTROLES"
           ContactRole="CENTRAL CONTACT"/>
   </ctr:InstitutionalReviewBoardEthicsCommittee>
   <!-- national oversight authorities -->
   <ctr:OversightAuthority CountryCode="USA" CodeListOID="CL.COUNTRIES"
        Name="Federal Government">
      <ctr:OrganizationRef OrganizationOID="ORG.USFEDGOV"/>
   </ctr:OversightAuthority>
   <ctr:OversightAuthority CountryCode="GER" CodeListOID="CL.COUNTRIES"
        Name="Paul-Ehrlich-Institut">
      <ctr:OrganizationRef OrganizationOID="ORG.PAULEHRLICH"/>
   </ctr:OversightAuthority>
</ctr:Authorities>
```

4.3.2.11 Other Organizations

The CDISC ODM element *Organization* is defined as a child element of the *User* element in *AdminData* and is "text only". This means that *Organization* cannot be extended. Therefore a new element *ctr:Organization* has been defined. It is expected that in the next version of the ODM standard the *Organization* element will be revised and aligned with the *ctr:Organization* element. *ctr:Organization* is a child element of the optional ODM *AdminData* element.

The *ctr:Organization* element includes an *OID* identifier attribute and can be referenced by the *ctr:OrganizationOID* attribute in other elements. The *ctr:Organization* element contains optional child elements: *Address*, *Email*, *Fax*, *Certificate*, and *ctr:Role*.

4.3.2.5.3 Example of the Other Organizations

```
<ctr:Organization OID="ORG.GRAZUNIVERSITYHOSPITAL" Name="Graz General
     Hospital">
   <Address>
      <StreetName>Auenbrugger Platz 1</StreetName>
      <City>Graz</City>
      <StateProv>Styria</StateProv>
      <Country>Austria</Country>
      <PostalCode>8036</PostalCode>
   </Address>
   <Email>info@graz.at</Email>
   <Fax>+43 555 5555</Fax>
   <Certificate></Certificate>
   <ctr:Role>Responsible site</ctr:Role>
</ctr:Organization>
```

4.3.3 EudraCT-Specific Information

The ***EudraCT protocol related data dictionary*** is a spreadsheet that lists the elements required to register a trial in the EMA trial registry. The spreadsheet is available online at https://eudract.ema.europa.eu/protocol.html. A summary of the elements that are required for

EudraCT submissions, but not covered by the WHO core elements outlined in Section 4.2 is provided in the following table.

Section	Item	CTR-XML approach
A. Trial Identification	Sponsor protocol version Sponsor protocol version date	CTR-XML extension to ODM *Protocol* element
B. Sponsor Identification	Legal Representative Identification Details	Legal Representative added to Controlled Terminology for *ctr:Contact* element.
C. Applicant Information	NA	
D. Description of the Investigational Medicinal Product (IMP)	IMP identification and Status Details IMP subject of scientific advice IMP Active Substance details Somatic Cell Therapy IMP Gene Therapy IMP Tissue Engineered Product Products containing devices Information on Placebo Manufacturing Sites	Use existing EudraCT-XML schema elements for IMP with *ctr:Intervention* element.
E. General Information on the Trial	Has sub-study Sub-study details Comparator Trial involving sites outside the EEA	Use SDM-XML *sdm:Parameter*. Use CTR-XML ctr:*RecruitmentCountry* element
F. Population of Trial Subject	Age Range Gender	Use existing EudraCT-XML elements.
G. Clinical Trial Sites/Investigators in the Member State	Investigator Details Clinical Trial Facility (CTF) Organization Details Network organization details	Use *ctr:Contact* element. Use ODM *User* element. Use ODM *User* element and *ctr:Contact* element.
H. Competent Authority/Ethics Committee	NCA Organization NCA Address Authorization	Use *ctr:Organization* and the ODM *Address* elements Use *ctr:Registration* element.

Much of the EudraCT specific information, not required by other registries, are key-value pairs that can be handled by Study Design Parameters, implemented as *sdm:Parameter* elements in the Study Design Model (SDM-XML).

The following EudraCT detailed information requirements are met by the providing *sdm:Parameter* elements:

Parameter Short Name	Term	EudraCT element	Allowed values / comments
EURSBIND*	EudraCT Resubmission Indicator*	Section A.7 Trial Identification	Yes/No
RESUBLTR*	Resubmission Letter*	Section A.7 Trial Identification	Usually designated with a subsequent letter ("A", "B", …)
SPONSTAT	Sponsor Status	Section B.3.1/B.3.2 Status of the Sponsor	Commercial / Non-commercial
PIPIND*	Pediatric Investigation Plan Indicator*	Section A8 EMA Decision number of	Yes / No

Parameter Short Name	Term	EudraCT element	Allowed values / comments
		Pediatric Investigation Plan	
EMPIPDCN*	EMA Decision Number for PIP*	Section A8 EMA Decision number of Paediatric Investigation Plan	Format "P/xxx/yyyy"
SRNCAIND*	SUSAR Reporting to NCA Indicator*	Section B.5.7 SUSAR reporting	Yes / No
SREVIND*	SUSAR Reporting to EVCTM Indicator*	Section B.5.7 SUSAR reporting	Yes / No
EVSNDID*	EudraVigilance Sender ID*	Section B.5.8 EV Sender ID	
EVSNDORG*	EudraVigilance Sender Organization*	Section B.5.8 EV Sender ID	
RDIND*	Rare Disease Indicator*	Section E.1.3	Yes / No
SSTDYIND*	Substudy Planned Indicator*	Section E.2.3 Objective of the trial	Yes / No
SSTDYDTL*	Substudy Details*	Section E.2.3 Objective of the trial	
TRIALSCO	EudraCT Trial Scope	Section E.6	Diagnosis / Prophylaxis / Therapy / Safety / Efficacy / Pharmacokinetic / Pharmacodynamic / Bioequivalence / Dose response / Pharmacogenetic / Pharmacogenomic / Pharmacoeconomic / Others

Note that the controlled terminology for the parameter *ShortName* and *Term* attributes is still under revision of the CDISC Controlled Terminology Team, as are the allowed values when these are enumerated.

4.3.3.1 Example for EudraCT Is Resubmission Trial Identification Parameter

```
<sdm:Parameter OID="PAR.EURSBIND" ShortName="EURSBIND"
      Term="EudraCT Resubmission Indicator">
   <sdm:Value>Yes</sdm:Value>
</sdm:Parameter>
```

EudraCT has additional requirements for information about **investigators**. Most of this information is provided by the ODM *User* element (a child element of the ODM *AdminData* element). For investigators, the attribute *UserType* has the value "Investigator".

New extension elements have been developed within the ODM User element, including *ctr:Role* and *ctr:Qualifications*. The ctr:Qualifications element contains free text information describing the qualifications of the user.

Business Rule:

- In the case of EudraCT, ctr:Qualifications text content is limited to 50 characters.

4.3.3.2 Example for EudraCT User Information

```
<Study OID="2A2-MC-EFGH" ctr:ResponsiblePartyType="PrincipalInvestigator">
   <GlobalVariables>
   …
   <ctr:Authorities >
      <ctr:FDAInformation IsFDARegulatedIntervention="No" IsINDNDEProtocol="No"
           HasDataMonitoringCommittee="No"/>
      <ctr:OversightAuthority CountryCode="ITA" CodeListOID="CL.Countries"
           Name="The Italian Medicines Agency">
         <ctr:OrganizationRef OrganizationOID="ORG.1"/>
      </ctr:OversightAuthority>
   </ctr:Authorities>
</Study>
…
<AdminData>
   <User OID="U.1" UserType="Investigator">
      <FullName>Luca Gallelli, MD</FullName>
      <Email>Gallelli@unicz.it</Email>
      <ctr:Role Context="EudraCT" RoleCodeListOID="CL.EUDRACTRoles">
         Primary Investigator
      </ctr:Role>
   </User>
   <ctr:Organization OID="ORG.1" Name="University of Cantanzaro"/>
</AdminData>
```

4.3.3.3 Central Technical Facility (CTF) Information

Central Technical Facilities are organizations, and should thus be listed under *ctr:Organization*. The element *ctr:CentralTechnicalFacilities* which comes under *AdminData* contains one or more *ctr:CentralTechnicalFacility* elements, each referencing a technical facility organization using a *ctr:OrganizationRef* child element. A contact person may be added using the *ctr:Contact* element referencing an ODM *User* element.

EudraCT also requires that the duties of each CTF are listed. This is done using the *ctr:CentralTechnicalFacilityDuty* element, which has the following enumerated values:

- has_duty_routine_cl_pathology
- has_duty_clinical_chemistry
- has_duty_clinical_haematology
- has_duty_clinical_microbiology
- has_duty_histopathology
- has_duty_serology_endocrinolog
- has_duty_analytical_chemistry
- has_duty_ecg_analysis
- has_duty_medical_img_analysis
- has_duty_endpoint_test
- has_duty_other_duties

To allow for future changes in EudraCT, these enumerations have not been hardcoded in the XML-Schema, but are represented in an ODM *CodeList* element referenced using the *CodeListOID* attribute on the *ctr:CentralTechnicalFacilityDuty* element.

Mapping to EudraCT: if a duty is not listed for a specific CTF, this maps to "false" in EudraCT section G.3.8

4.3.3.4 Example for EudraCT Central Technical Facility Information

```
<ctr:CentralTechnicalFacilities>
   <ctr:CentralTechnicalFacility>
      <ctr:OrganizationRef OrganisationOID="ORG.MYCENTRALLAB"/>
      <ctr:Contact UserOID="CONT.CENTRALLABCONTACT"/>
      <ctr:CentralTechnicalFacilityDuty CodeListOID="CL.EUDRACTCTFDUTIES">
         has_duty_clinical_chemistry
      </ctr:CentralTechnicalFacilityDuty>
      <ctr:CentralTechnicalFacilityDuty CodeListOID="CL.EUDRACTCTFDUTIES">
         has_duty_analytical_chemistry
      </ctr:CentralTechnicalFacilityDuty>
   </ctr:TechnicalFacility>
</ctr:CentralTechnicalFacilities>
```

4.3.3.5 Interventions and Medicinal Products

EudraCT requires a large amount of information about interventions that is in addition to and not compatible with the WHO requirements identified under TRDS-13 in Section 4.2.8.

In CTR-XML the EudraCT-XML element *medicinal_product_information* exists as a child element of the ODM *Study* element, but in such a way that it remains in the EudraCT namespace http://eudract.emea.europa.eu/schema/clinical_trial. This can be accomplished in the two ways.

In the first way, the EudraCT namespace is declared at the top of the ODM element and is bound to the namespace http://eudract.emea.europa.eu/schema/clinical_trial.

```
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
     xmlns:sdm="http://www.cdisc.org/ns/studydesign/v1.0"
     xmlns:ctr="http://www.cdisc.org/ns/ctr/v1.0"
     xmlns:ct="http://eudract.emea.europa.eu/schema/clinical_trial">
```

The ct: prefix is used to indicate the specific namespace, when used as shown in the *Study* element example below:

```
<Study ctr:StudyType="Interventional">
   <!-- here come all the normal ODM and SDM XML elements -->
   <!-- followed by the EudraCT "medicinal_product_information" bound by the "ct"
        prefix -->
   <ct:medicinal_product_information>
      <ct:medicinal_product>
         <!-- here come the details -->
      </ct:medicinal_product>
   </ct:medicinal_product_information>
   …
</Study>
```

The second way is to provide the namespace declaration within the *medicinal_product_information* element itself, as is shown in the following example:

```
<ct:medicinal_product_information
     xmlns:ct="http://eudract.emea.europa.eu/schema/clinical_trial">
   <ct:medicinal_product>
      …
   </ct:medicinal_product>
</ct:medicinal_product_information>
```

4.4 Use of sdm:Parameter

The SDM-XML extension to the ODM has a "trial summary" containing "trial parameters", which are also used in CDISC SDTM for submissions to regulatory authorities. The idea of including these into SDM-XML was that ODM + SDM-XML[3] contains all information for an end-to-end solution, i.e. that sponsors and users can already define information that will later flow into SDTM tables before study start allowing automated SDTM generation later.

Many of these "trial parameters" are also required by CTRs. So it was decided to use SDM-XML *sdm:Parameter* as much as possible for these parameters that are required by CTRs. This has the advantage that exactly the same trial parameter information that is submitted to a CTR can also be submitted in the SDTM (TS domain) later, without discrepancies ("write once, use many" principle).

In some cases the allowable values for a parameter differ across different trial registries. For example, for the parameter "Trial Phase", the number as well as the designation of the trial phases are different across the registries including ClinicalTrials.gov controlled terminology, EudraCT controlled terminology, and CDISC (SDTM) Controlled Terminology.

An extended attribute *ctr:Scope* has been added to the SDM-XML element *sdm:Value* to be used to define the applicable scope when defining certain parameters. If no *ctr:Scope* attribute is provided, the default scope is "CDISC".

In that case, the value for the parameter "TPHASE" is submitted 2 or more times with different *ctr:Scope* attribute values, as is shown in the following example:

```
<sdm:Parameter OID="PAR.TPHASE" ShortName="TPHASE" Term="Trial Phase">
   <sdm:Value>Phase IIb Trial</sdm:Value>
   <sdm:Value ctr:Scope="EudraCT">Therapeutic Exploratory (Phase II)</sdm:Value>
   <sdm:Value ctr:Scope="ClinicalTrials.gov">Phase 2</sdm:Value>
</sdm:Parameter>
```

The use of *ctr:Scope* has been limited to a few cases only, where it was inevitable.

[3] It is envisaged that SDM-XML will flow into core ODM in the future.

5 Specification

5.1 CTR-XML Scope

A CTR-XML file provides the metadata for the study design subset for clinical trial registry submissions, including the 20 WHO Trial Registration Data Set (TRDS) items, to the following:

- World Health Organization (WHO)
- European Medicines Agency (EMA) EudraCT Registry
- United States' ClinicalTrials.gov clinical trials registry

The CTR–XML standard provides an approach for generating harmonized messages to each of the three agencies listed, but does not provide a unified message that can be submitted directly to the all registries. CTR-XML currently does not include submissions of clinical trials results.

5.2 CTR-XML Structure

CTR-XML is based on the CDISC ODM standard, but also incorporates the SDM-XML schema and elements of the EudraCT-XML schemas to provide an overall cross-registry schema.

A CTR-XML file includes the following key content components:

- XML header
- ODM root element
- Study
- MetaDataVersion
- Protocol
- CodeLists
- Recruitment
- Interventions
- OutcomeMeasures
- StudyStartDate
- StudyEndDate
- StudyEndDatePrimaryOutcome
- medicinal_product_information
- population_information
- AdminData
- Users
- Organizations

The sections that follow describe what a CTR-XML file can contain. Each of the elements is described in the sections below in the order in which they occur in the XML. Elements that may be used in more than one context are presented where they first appear in the document.

Note that the section hierarchy in this document does not reflect the XML structure. For example, the *ODM* and *Study* elements are described at the same level in this document, however, the *Study* element in the XML is a child of the *ODM* element.

Each section begins with a brief description of the element. This is then followed by an *element table*, and an *attribute table*. In a few cases, a section or sub-section concludes with an XML example, however most examples are provided in Section 4, General Specifications for CTR-XML.

An *element table* describes the different aspects of an element's definition while the *attribute table* describes the element's attributes. The following templates illustrate the layouts of these tables, including headers and descriptions of the content.

Element Table Template

Element Name:	*Name of the element*
Element XPath:	*XPath showing where the element belongs in the XML*
Element Textual Value:	*A description of the value of the element. If an element has no text value (e.g. it has child elements instead), then this cell is populated with "None".*
Usage:	*Requirement: This is populated with one of three values:* • *"Required" when at least one instance of the element is required* • *"Optional" when the element is optional* • *"Conditional" when at least one instance of the element is required under certain conditions. It will include the conditions under which the element is Required.* *Cardinality: This indicates the number of instances expected (e.g. "1", "1 or more", etc.)* *Business Rule(s): This is populated with rules that have to be satisfied in addition to an XML schema validation for a CTR-XML document to be considered compliant with the CTR-XML v1.0.0 specification.* *Other Information: This is populated with any other information about the element, including the conditions under which the element is included, how the schema is applied to support the model, relative position of the element in the model, etc.*
Attributes:	*A comma-delimited list of the attributes of this element. If the element has no attributes, this is populated with "None".*
Child Elements:	*A comma-delimited list of the immediate child elements of this element. If the element has no child elements, this is populated with "None". The order of child elements shown in the specification is the order in which they must appear in an CTR-XML document.* *A link to a child element will be provided when the child element is described in a different section of the document and not under a sub-section of the element being described or in the section or subsection immediately following the current element.*

Attribute Table Template

Attribute	Usage	Allowable Values	Description
Name of the attribute	*This is populated with "Required" when the attribute is required, "Optional" when the attribute is optional, or "Conditional" when the attribute is required under certain conditions.* *It will include the conditions under which the attribute is Required.* *Default: This will be populated with a default value if one is provided in the specification.*	*Any combination of the following:* *Data Type: The ODM datatype of the value* *Allowable Value: The only allowed value* *Allowable Values: A comma-delimited list of the allowable values* *Value Description: A textual description of allowable values* *See Appendix xx: A reference to an appendix including a hyperlink to the appendix* *Sample: An example*	*A textual description of the attribute beyond what is included in the Allowable Values column.* *Business Rule(s): Rules that have to be satisfied in addition to schema validation for an CTR-XML document to be considered compliant with the CTR-XML v1.0.0 specification.*

5.3 CTR-XML Specification Details

5.3.1 XML Header

The first line of an CTR-XML file must be the XML header. The XML header indicates that the remainder of the file is XML and specifies the character encoding it uses.

5.3.1.1 Example XML Header

```
<?xml version="1.0" encoding="UTF-8"?>
```

This example XML header shows an CTR-XML file using the "UTF-8" character encoding.

5.3.2 ODM Element

The first XML element in a file is known as the root element. In CTR-XML the *ODM* element is the root element. The *ODM* element identifies the namespaces used, and includes attributes that affect the processing of the document as a whole.

Element Name:	ODM
Element XPath:	/ODM
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: This is the root element for the CTR-XML document
Attributes:	xmlns, xmlns:ctr, xmlns:sdm, xmlns:xlink, xmlns:xsi, xsi:schemalocation, Description, ODMVersion, FileType, FileOID, CreationDateTime, AsOfDateTime, Originator, SourceSystem, SourceSystemVersion, Granularity, ctr:CTRXMLVersion
Child Elements:	Study, AdminData

Attribute	Usage	Allowable Values	Description
xmlns	Required	"http://www.cdisc.org/ns/odm/v1.3"	Identifies the default namespace for this document.
xmlns:sdm	Required	"http://www.cdisc.org/ns/studydesign/v1.0"	XML namespace for SDM-XML v1.0.
xmlns:ct	Required	"http://eudract.emea.europa.eu/schema/clinical_trial"	XMLnamespace for EudraCT.
xmlns:ctr	Required	"http://www.cdisc.org/ns/ctr/v1.0"	XMLnamespace for CTR-XML extension.
xsi:schemalocation	Optional	text Sample: "http://www.cdisc.org/ns/CTR-XML/v1.0 dataset1-0-0.xsd"	Identifies the location of the schema for this XML document. The first part is the Namespace URI, and the second part is the location of the schema either on the internet (e.g. http://www.abc.com/ctr-ns-1-0-0.xsd) or on the local file system (e.g. ctr-ns-1-0-0.xsd). Using a local copy of the schema rather than referencing a schema using a URL on the web is recommended as it improves the probability that the software validating the CTR-XML instance can find and access the appropriate files. However, when submitting CTR-XML files to a regulatory authority, be aware that relative file references or references to a shared drive on a local area network may not work when the submission contents are transmitted to a different network location.

Attribute	Usage	Allowable Values	Description
ODMVersion	Required	"1.3.2.1"	Identifies the ODM version that underlies the schema for the CTR-XML document. ODMVersion is optional in the ODM standard, but required in CTR-XML.
FileType	Required	"Snapshot"	CTR-XML documents do not include audit trail elements, so the FileType is Snapshot.
FileOID	Required	text	A unique identifier for this file. See the ODM specification for a discussion of *FileOID* recommendations.
Granularity	Optional	"Metadata"	*Granularity* is intended to give the sender a shorthand way to describe the breadth of the information in the document.
Description	Optional	text	The sender should use the *Description* attribute to record any information that will help the receiver interpret the document correctly.
CreationDateTime	Required	ISO 8601 datetime Sample: "2013-09-30T15:31:04"	The date and time when the specific version of the CTR-XML file was created. This is the "last modified" date and time.
AsOfDateTime	Optional	ISO8601 datetime Sample: "2013-09-30T15:31:04"	The date and time at which the source database was queried to create this document.
Originator	Optional	text Sample: "Company XYZ"	Submission sponsor name
SourceSystem	Optional	text	The name of the application that generated the CTR-XML file.
SourceSystemVersion	Optional	text	The version of the "SourceSystem" above.
ctr:CTRXMLVersion	Required	"1.0.0"	The version of the CTR-XML standard ctr:CTRXMLVersion.

5.3.3 Study Element

Study is the first element in the Define-XML document after the *ODM* element.

Element Name:	Study
Element XPath:	/ODM/Study
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: The child element GlobalVariables contains child ele that capture high level study information. The child element MetaDataV includes child elements to describe a collection of Datasets.
Attributes:	OID, ctr:ResponsiblePartyType
Child Elements:	GlobalVariables, MetaDataVersion, ctr:StudyStartDate, ctr:StudyEndDate, ctr:StudyEndDatePrimaryOutcome, ct:medicinal_product_information, ct:population_information

Attribute	Usage	Allowable Values	Description
OID	Required	text	The unique ID of the Study. See the ODM specification section 2.11 for OID considera
ctr:ResponsiblePartyType	Conditional Business Rules: Required for ClinicalTrials.gov	"Sponsor", "Principal Investigator", "Sponsor-Investigator"	Business Rules: When value is Sponsor, a User/ Organization must be provided. When value is "Principal Investigator" or "Sponsor-Investigator", User/FullName must be provided.

5.3.3.1 GlobalVariables Element

GlobalVariables is the first child of *Study*.

Element Name:	GlobalVariables
Element XPath:	/ODM/Study/GlobalVariables
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: High-level study information.
Attributes:	*None*
Child Elements:	StudyName, StudyDescription, ProtocolName, ctr:Authorities, ctr:PublicTitle, ctr:StudyDetailedDescription, ctr:Registrations, ctr:FundingSupport, ctr:Contacts

5.3.3.1.1 StudyName Element

StudyName is the first child of *GlobalVariables*.

Element Name:	StudyName
Element XPath:	/ODM/Study/GlobalVariables/StudyName
Element Textual Value:	WHO: Scientific title EudraCT: Full title ClinicalTrials.gov: Official title
Usage:	Requirement: Required Cardinality: 1
Attributes:	*None*
Child Elements:	ctr:StudyNameLocalizations

5.3.3.1.1.1 ctr:StudyNameLocalizations Element

The *ctr:StudyNameLocalizations* element provides a container for translations of the *StudyName* into one or more additional languages.

Element Name:	ctr:StudyNameLocalizations
Element XPath:	/ODM/Study/GlobalVariables/StudyName/ctr:StudyNameLocalizations
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 1 Other Information: The *ctr:StudyNameLocalizations* element is required as a container for two or more TranslatedText elements when the WHO Scientific Title or the EudraCT Full title or the ClinicalTrials.gov Official title will be provided in two or more languages.
Attributes:	*None*
Child Elements:	TranslatedText

5.3.3.1.1.1.1 TranslatedText Element

Element Name:	TranslatedText
Element XPath(s):	/ODM/Study/GlobalVariables/StudyName/ctr:StudyNameLocalizations/ TranslatedText /ODM/Study/GlobalVariables/ctr:PublicTitle/TranslatedText /ODM/Study/GlobalVariables/ctr:StudyDetailedDescription/TranslatedText
Element Textual Value:	Text
Usage:	Requirement: Required Cardinality: One or more. • Multiple TranslatedText child elements can be used to provide the dataset description in different languages. One for each language the description is desired.
Attributes:	xml:lang
Child Elements :	*None*

Attribute	Usage	Allowable Values	Description
xml:lang	Optional Default: "en"	Allowable Values: see: http://www.rfc-editor.org/rfc/bcp/bcp47.txt Samples: "en" for English "en-GB" for British English	Code representing the language of the enclosed text value. Business Rule: xml:lang should be unique within parent element.

5.3.3.1.2 StudyDescription Element

StudyDescription is the second child of GlobalVariables.

Element Name:	StudyDescription
Element XPath:	/ODM/Study/GlobalVariables/StudyDescription
Element Textual Value:	A text description of the contents of the Study.
Usage:	Requirement: Required Cardinality: 1 Other Information: Usually found in the high level description of the study Protocol document.
Attributes:	*None*
Child Elements:	*None*

5.3.3.1.3 ProtocolName Element

ProtocolName is the third child of GlobalVariables.

Element Name:	ProtocolName
Element XPath:	/ODM/Study/GlobalVariables/ProtocolName
Element Textual Value:	The sponsor's internal name assigned to the Study
Usage:	Requirement: Required Cardinality: 1 Other Information: Usually found in the high level description of the study in the Protocol document.
Attributes:	*None*
Child Elements:	*None*

5.3.3.1.4 ctr:Authorities Element

The ctr:Authorities element provides details about the registration authority.

Element Name:	ctr:Authorities
Element XPath:	/ODM/Study/GlobalVariables/ctr:Authorities
Element Textual Value:	The sponsor's internal name assigned to the Study
Usage:	Requirement: Conditional Cardinality: 1
Attributes:	*None*
Child Elements:	ctr:FDAInformation, ctr:InstitutionalReviewBoardEthicsCommittee, ctr:OversightAuthority

5.3.3.1.4.1 ctr:FDAInformation Element

Element Name:	ctr:FDAInformation
Element XPath:	/ODM/Study/GlobalVariables/ctr:Authorities/ctr:FDAInformation
Element Textual Value:	Contains the information required by ClinicalTrials.gov
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	IsFDARegulatedIntervention, IsINDNDEProtocol, HasDataMonitoringCommittee
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
IsFDARegulatedIntervention	Required	text "Yes" or "No"	
IsINDNDEProtocol	Required	text "Yes" or "No"	
HasDataMonitoringCommittee	Optional	text "Yes" or "No"	

5.3.3.1.4.2 ctr:InstitutionalReviewBoardEthicsCommittee Element

This element contains the information about and status of a study in an institutional review board and ethics committee.

Element Name:	ctr:InstitutionalReviewBoardEthicsCommittee
Element XPath:	/ODM/Study/GlobalVariables/ctr:Authorities/ ctr:InstitutionalReviewBoardEthicsCommittee
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, ApprovalStatus
Child Elements:	ctr:OrganizationRef, ctr:Contact

Attribute	Usage	Allowable Values	Description
OID	Required		See the ODM specification section 2.11 for OID considerations.
ApprovalStatus	Required	"Request not yet submitted", "Submitted, pending", "Submitted, approved", "Submitted, exempt", "Submitted, denied", "Submission not required"	

5.3.3.1.4.2.1 ctr:OrganizationRef Element

Reference to a ctr:Organization element, containing the detailed information about the oversight authority.

Element Name:	ctr:OrganizationRef
Element XPath:	/ODM/Study/GlobalVariables/ctr:Authorities/ ctr:InstitutionalReviewBoardEthicsCommittee/ctr:OrganizationRef /ODM/AdminData/User/ctr:OrganizationRef /ODM/AdminData/ctr:CentralTechnicalFacilities/ ctr:CentralTechnicalFacility/ctr:OrganizationRef /ODM/AdminData/ctr:Neworks/ctr:CentralNetwork/ctr:OrganizationRef /ODM/AdminData/ctr:SubContractors/ctr:SubContractor/ ctr:OrganizationRef /ODM/Study/GlobalVariables/ctr:Authorities/ ctr:InstitutionalReviewBoardEthicsCommittee/ctr:OrganizationRef /ODM/Study/GlobalVariables/ctr:Authorities/ctr:OversightAuthority/ ctr:OrganizationRef
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1
Attributes:	OrganizationOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
OrganizationOID	Required	text	References an Organization within this CTR-XML file.

5.3.3.1.4.2.2 ctr:Contact Element

The *ctr:Contact* element is used to transmit the contact information for the primary contact, the contact for scientific queries (WHO) and the contact for public queries (WHO).

Element Name:	ctr:Contact
Element XPath(s):	/ODM/Study/GlobalVariables/ctr:Authorities/ ctr:InstitutionalReviewBoardEthicsCommittee/ctr:Contact /ODM/Study/GlobalVariables/StudyName/ctr:Contacts/ctr:Contact
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more At least 1 ctr:Contact is required within ctr:Contacts
Attributes:	UserOID, ContactRole, ContactRoleCodeListOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
UserOID	Required	text	References a *User* element within the *AdminData*
ContactRole	Required	text	If a Codelist is referenced, the value of ContactRole must match the CodedValue attribute for a CodeListItem or EnumeratedItem in the corresponding CodeList.
ContactRoleCodeListOID	Required	See provisional controlled terminology in table in Section 4.2.3	References a *Codelist* within the *MetaDataVersion* element. An ODM *Codelist* must be provided within the CTR-XML file to provide the list of Contact Roles.

5.3.3.1.4.3 ctr:OversightAuthority Element

This element contains information about national oversight authorities, including NCAs (National Competent Authorities) for which the registration applies.

Element Name:	ctr:OversightAuthority
Element XPath:	/ODM/Study/GlobalVariables/ctr:Authorities/ctr:OversightAuthority
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	CountryCode, CodeListOID, Name
Child Elements:	ctr:OrganizationRef

Attribute	Usage	Allowable Values	Description
Name	Required	text	Short name of the oversight authority
CountryCode	Required	ISO-codes (e.g. ISO 3166-1 alpha-3)	
CodeListOID	Required	text	data type odm:oidref - reference to an internal or external codelist with country codes

5.3.3.1.5 ctr:PublicTitle Element

Element Name:	ctr:PublicTitle
Element XPath:	/ODM/Study/GlobalVariables/ctr:PublicTitle
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: • For WHO this is the PublicTitle • For ClinicalTrials.gov this is the BriefTitle • For EudraCT this is the lay people title

Attributes:	*None*
Child Elements:	TranslatedText

5.3.3.1.6 ctr:StudyDetailedDescription Element

The *ctr:StudyDetailedDescription* element provides a detailed description of the study that goes beyond the basic description provided by the study title.

Element Name:	ctr:StudyDetailedDescription
Element XPath:	/ODM/Study/GlobalVariables/ctr:StudyDetailedDescription
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for ClinicalTrials.gov submissions
Attributes:	*None*
Child Elements:	TranslatedText

5.3.3.1.7 ctr:Registrations Element

Container element for one or more Registration elements.

Element Name:	ctr:Registrations
Element XPath:	/ODM/Study/GlobalVariables/ctr:Registrations
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	*None*
Child Elements:	ctr:Registration

5.3.3.1.7.1 ctr:Registration Element

Contains registration details.

Element Name:	ctr:Registration
Element XPath:	/ODM/Study/GlobalVariables/ctr:Registrations/ctr:Registration
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	Type, RegistrationDate, RegistrationAuthority, RegistrationID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Type	Required	"Primary", "Secondary", "Universal", "Other"	Business Rules: If the RegistrationID is a WHO UTN, the Type attribute must be "Universal".
RegistrationDate	Conditional Business Rule: Required when Type="Primary" Optional otherwise	ISO8601 datetime Sample: "2015-05-26"	WHO: Date of Registration in Primary Registry
RegistrationAuthority	Required	"ClinicalTrials.gov" "EudraCT"" "WHO"	CDISC controlled terminology may be required in future.
RegistrationID	Required	text	ClinicalTrials.gov: EudraCT Number

5.3.3.1.8 ctr:FundingSupport Element

Element Name:	ctr:FundingSupport
Element XPath:	/ODM/Study/GlobalVariables/ctr:FundingSupport
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	*None*
Child Elements:	ctr:Sponsor

5.3.3.1.8.1 ctr:Sponsor Element

Element Name:	ctr:Sponsor
Element XPath:	/ODM/Study/GlobalVariables/ctr:FundingSupport/ctr:Sponsor
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more Other Information: • EudraCT does not make a distinction between primary and secondary sponsors or sources of monetary support. This means that the attribute *SponsorType* should be omitted by applications that work in the scope of a EudraCT submission. If the information is meant to be submitted to EudraCT only, the *SponsorType* attribute can be omitted. In case the information is meant to or could be submitted to ClinicalTrials.gov, the *SponsorType* attribute is required. • The attribute *SponsorType* should either appear on all *Sponsor* elements within *ctr:FundingSupport* or on neither of them. • Within the element *ctr:FundingSupport*, only one child element Sponsor can have the *SponsorType* attribute with the value "Primary". • One of the attributes *OrganizationOID* or *UserOID* must be included, but not both.
Attributes:	SponsorType, FundingID, OrganizationOID, UserOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
SponsorType	Conditional See Other Information above.	"Primary", "Secondary"	
FundingID	Optional To be used when a grant, funding number or ID is available.	text	Reference to a grant of funding ID or number.
OrganizationOID	Conditional: Required if UserOID is not provided	text	Reference to an AdminData/ctr:Organization element within this CTR-XML file.
UserOID	Conditional: Required if OrganizationalOID is not provided	text	Reference to an AdminData/User element within this CTR-XML file.

5.3.3.1.9 ctr:Contacts Element

Element Name:	ctr:Contacts
Element XPath:	/ODM/Study/GlobalVariables/ctr:Contacts
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	ctr:Contact

5.3.3.2 MetaDataVersion Element

The *MetaDataVersion* element is used for providing one or more versions of the metadata of the study.

Element Name:	MetaDataVersion
Element XPath:	/ODM/Study/MetaDataVersion
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1
Attributes:	OID, Name, Description
Child Elements:	Protocol, StudyEventDef, FormDef, ItemGroupDef, CodeList, ConditionDef, MethodDef, ctr:Recruitment, ctr:Interventions, ctr:OutcomeMeasures

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the MetaDataVersion. See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Name for the *MetaDataVersion*.
Description	Optional	text Sample: "Study design for CDISC01 version 1.0"	Description for the *MetaDataVersion*.

5.3.3.2.1 Protocol Element

Element Name:	Protocol
Element XPath:	/ODM/Study/MetaDataVersion/Protocol
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: Will not generally contain StudyEventRef elements in CTR-XML.
Attributes:	ctr:ProtocolID, ctr:ProtocolVersion, ctr:ProtocolVersionDate, ctr:ProtocolVersionChangeDate
Child Elements:	Description, StudyEventRef, Alias, sdm:Summary, sdm:InclusionExclusionCriteria, sdm:Structure

Attribute	Usage	Allowable Values	Description
ctr:ProtocolID	Required Business Rules: Required for EudraCT (sponsor protocol code) and for Clinical Trials.gov (Organizations's Unique Protocol ID)	text	Unique ID for the Protocol definition.
ctr:ProtocolVersion	Conditional Business Rules: Required for EudtraCT submissions.	text	Sponsor protocol version.
ctr:ProtocolVersionDate	Conditional Business Rules: Required for EudtraCT submissions.	date in ISO8601 format.	Date of current protocol version

Attribute	Usage	Allowable Values	Description
ctr:ProtocolVersionChangeDate	Conditional Business Rules: Required for EudtraCT submissions when previous versions of the protocol exist.	date in ISO8601 format	Date of last change to current protocol.

5.3.3.2.1.1 Description Element

ODM Description element.

Element Name:	Description
Element XPath(s):	/ODM/Study/MetaDataVersion/Protocol/Description /ODM/Study/MetaDataVersion/Protocol/sdm:Summary/Description /ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria/ Description /ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:Epoch/Description /ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:Arm/Description /ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef/Description /ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:SegmentDef/ Description /ODM/Study/MetaDataVersion/ConditionDef/Description /ODM/Study/MetaDataVersion/ctr:Interventions/ctr:Intervention/Description /ODM/Study/MetaDataVersion/ctr:OutcomeMeasures/ctr:OutcomeMeasure/ Description /ODM/Study/MetaDataVersion/ctr:OutcomeMeasures/ctr:OutcomeMeasure/ ctr:*Timepoint*/Description
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	TranslatedText

5.3.3.2.1.2 StudyEventRef Element

StudyEventRef elements referencing StudyEventDef elements which essentially are detailed visit descriptions.

Element Name:	StudyEventRef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/StudyEventRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more Other Information: CTR-XML will not generally contain *StudyEventRef* elements.
Attributes:	StudyEventOID, OrderNumber, Mandatory
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
StudyEventOID	Required	text	Reference to the StudyEventDef OID.
OrderNumber	Optional	positiveInteger	The OrderNumbers provide an ordering on the StudyEventDefs for use whenever a list of StudyEventDefs is presented to a user. They do not imply anything about event scheduling, time ordering, or data correctness.
Mandatory	Required	"Yes" or "No"	The Mandatory flag indicates that the clinical data for the containing MetaDataVersion would be incomplete without an instance of this type of Study Event.

5.3.3.2.1.3 Alias Element

An *Alias* provides an additional name, or synonym, for an element. The *Context* attribute specifies the application domain in which this additional name is relevant.

Element Name:	Alias
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/Alias /ODM/Study/MetaDataVersion/StudyEventDef/Alias /ODM/Study/MetaDataVersion/ItemGroupDef/Alias /ODM/Study/MetaDataVersion/CodeList/Alias /ODM/Study/MetaDataVersion/CodeList/CodeListItem/Alias /ODM/Study/MetaDataVersion/CodeList/EnumeratedItem/Alias
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	Context, Name
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Context	Required	text	Indicates the context or setting where the Alias Name attribute applies.
Name	Required	text	Alternative Name for parent element.

5.3.3.2.1.4 sdm:Summary Element

The *sdm:Summary* element provides the ability to define a set of parameters to the study design.

Element Name:	sdm:Summary
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Summary
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: See Appendix B for a list of the trial summary parameters from the CDISC controlled terminology TSPARMCD / TSPARM that must be included in the sdm:Summary section of the ODM file as an sdm:Parameter
Attributes:	*None*
Child Elements:	Description, sdm:Parameter

5.3.3.2.1.4.1 sdm:Parameter Element

Each *sdm:Parameter* within *sdm:Summary* includes a term and optional short name, and comprises one or more corresponding values.

Element Name:	sdm:Parameter
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Summary/sdm:Parameter
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more Other Information: See Appendix B for a list of the trial summary parameters from the CDISC controlled terminology TSPARMCD / TSPARM that must be included in the sdm:Summary section of the ODM file as an sdm:Parameter
Attributes:	OID, Term, ShortName
Child Elements:	sdm:Value

Attribute	Usage	Allowable Values	Description
OID	Required	text	
Term	Required	text	

Attribute	Usage	Allowable Values	Description
ShortName	Required	text	Business Rules: May be subject to controlled terminology. See table in Appendix B.

5.3.3.2.1.4.1.1 sdm:Value Element

Element Name:	sdm:Value
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Summary/sdm:Parameter/sdm:Value
Element Textual Value:	Parameter value
Usage:	Requirement: Required Cardinality: One or more
Attributes:	DisplayValue, ctr:CodeListOID, ctr:Scope
Child Elements:	TranslatedText

Attribute	Usage	Allowable Values	Description
ctr:DisplayValue	Conditional	text	If the textual content for the sdm:Value element is a Code, the Display Value provides the text decode.
ctr:CodeListOID	Conditional	text	Reference to a CodeList element in this CTR-XML file.
ctr:Scope	Conditional	string	Use as needed to clarify scope or meaning of the specified parameter value.

5.3.3.2.1.4.2 Example Study Summary Including Parameter and Values

```
<sdm:Summary>
   <sdm:Parameter OID="PAR.AGESPAN" Term="Age Span" ShortName="AGESPAN">
      <sdm:Value>Adult (18-65)</sdm:Value>
      <sdm:Value>Elderly (&gt;65)</sdm:Value>
   </sdm:Parameter>
</sdm:Summary>
```

5.3.3.2.1.5 sdm:InclusionExclusionCriteria Element

The *sdm:InclusionExclusionCriteria* element can contain two lists of Criterion elements, represented by *sdm:InclusionCriteria* and *sdm:ExclusionCriteria*. Together these criteria determine the eligibility of a subject for the study.

Element Name:	sdm:InclusionExclusionCriteria
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1
Attributes:	*None*
Child Elements:	Description, sdm:InclusionCriteria, sdm:ExclusionCriteria

5.3.3.2.1.5.1 sdm:InclusionCriteria Element

Element Name:	sdm:InclusionCriteria
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria/ sdm:InclusionCriteria
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	sdm:Criterion

5.3.3.2.1.5.1.1 sdm:Criterion Element

Element Name:	sdm:Criterion
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria/ sdm:InclusionCriteria/sdm:Criterion /ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria/ sdm:ExclusionCriteria/sdm:Criterion
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	OID, Name, ConditionOID
Child Elements:	None

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier
Name	Required	text	
ConditionOID	Required	text	OID of ConditionDef in this CTR-XML file.

5.3.3.2.1.5.1.1.1 Example of Inclusion and Exclusion Criteria

```
<sdm:InclusionExclusionCriteria>
   <Description>
      <TranslatedText xml:lang="en">Include subjects ...</TranslatedText>
   </Description>
   <sdm:InclusionCriteria>
      <sdm:Criterion OID="CRIT00" ConditionOID="AGECOND00" Name="Age Inclusion"/>
   </sdm:InclusionCriteria>
   <sdm:ExclusionCriteria>
      <sdm:Criterion OID="CRIT01" ConditionOID="AGECOND01" Name="Age Exclusion"/>
      <sdm:Criterion OID="CRIT02" ConditionOID="PREGNANCYCOND"
           Name="Pregnancy Exclusion"/>
   </sdm:ExclusionCriteria>
</sdm:InclusionExclusionCriteria>
```

5.3.3.2.1.5.2 sdm:ExclusionCriteria Element

Element Name:	sdm:ExclusionCriteria
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:InclusionExclusionCriteria/ sdm:ExclusionCriteria
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	sdm:Criterion

5.3.3.2.1.6 sdm:Structure Element

Element Name:	sdm:Structure
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1
Attributes:	*None*
Child Elements:	sdm:Epoch, sdm:Arm, sdm:CellDef, sdm:SegmentDef, sdm:ActivityDef

5.3.3.2.1.6.1 sdm:Epoch Element

Element Name:	sdm:Epoch
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:Epoch
Element Textual Value:	*None*

Usage:	Requirement: Conditional Cardinality: 0 or more Other Information: Required for cross-over studies.
Attributes:	OID, Name, OrderNumber
Child Elements:	Description

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Name for this *Epoch*.
OrderNumber	Required	integer	Display order of the *Epoch* within the sdm:Arm.

5.3.3.2.1.6.2 sdm:Arm Element

Element Name:	sdm:Arm
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:Arm
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or more Other Information: Required for interventional studies.
Attributes:	OID, Name, ctr:InterventionOID, ctr:CTArmType
Child Elements:	Description

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Short name for study arm.
InterventionOID	Required	text	Business Rules: For WHO CTR Submissions the intervention must be defined for each Arm.
ctr:CTArmType	Conditional Business Rules: Mandatory in the scope of a ClinicalTrials.gov submission.	text "Experimental", "Active Comparator", "Placebo Comparator", "Sham Comparator", "No intervention", "Other"	

5.3.3.2.1.6.3 sdm:CellDef Element

Element Name:	sdm:CellDef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or more Other Information: Required for cross-over studies when submitting to the WHO.
Attributes:	OID, Name, EpochOID
Child Elements:	Description, sdm:ArmAssociation, sdm:SegmentRef

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Short name for the cell.

Attribute	Usage	Allowable Values	Description
EpochOID	Required	text	OID of the Epoch in which the cell is contained. Each sdm:*CellDef* element references exactly 1 *sdm:Epoch* element. An Epoch with the referenced OID must be within this CTR-XML file.

5.3.3.2.1.6.3.1 sdm:ArmAssociation Element

In a blinded study, the treatment cell cannot be assigned to a particular arm at design-time. Rather, a list of possible arm assignments is given within the cell's *sdm:ArmAssociation* element.

Element Name:	sdm:ArmAssociation
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef/ sdm:ArmAssociation
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	Type
Child Elements:	sdm:ArmRef, ctr:BlindedRole

Attribute	Usage	Allowable Values	Description
Type	Required	"Blinded", "Unblinded"	Indication of whether or not the arms are blinded.

5.3.3.2.1.6.3.1.1 sdm:ArmRef Element

Element Name:	sdm:ArmRef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef/ sdm:ArmAssociation/sdm:ArmRef
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: One or more
Attributes:	ArmOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
ArmOID	Required	text	References a *sdm:Arm* element in this document.

5.3.3.2.1.6.3.1.2 ctr:BlindedRole Element

The *ctr:BlindedRole* element provides the additional details describing the blinding / masking performed as part of the study design.

Element Name:	ctr:BlindedRole
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef/ sdm:ArmAssociation/ctr:BlindedRole
Element Textual Value:	Role that is blinded or masked Note: The valid values are "Subject", "Investigator", "Monitor", "Data analyst", "Care provider", and "Assessor".
Usage:	Requirement: Conditional Cardinality: Zero or more Business Rules: Allowed only when the *sdm:ArmAssociationType* on the parent *sdm:ArmAssociation* element is "Blinded".
Attributes:	*None*
Child Elements:	*None*

5.3.3.2.1.6.3.2 sdm:SegmentRef Element

An *sdm:SegmentDef* element must be referenced by a cell via an *sdm:SegmentRef* within an *sdm:CellDef*.

Element Name:	sdm:SegmentRef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:CellDef/ sdm:SegmentRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	SegmentOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
SegmentOID	Required	text	Segment reference OID.

5.3.3.2.1.6.4 sdm:SegmentDef Element

A *sdm:SegmentDef* represents a set of activities.

Element Name:	sdm:SegmentDef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:SegmentDef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more Business Rules: • An *sdm:SegmentDef* may reference zero or more *sdm:ActivityDef* elements. Each such reference indicates an activity which is to be undertaken as part of that segment. • Any given *sdm:ActivityDef* should never be referenced more than once from the set of all *sdm:SegmentDefs* for a study.
Attributes:	OID
Child Elements:	Description, sdm:ActivityRef

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.

5.3.3.2.1.6.4.1 sdm:ActivityRef Element

Element Name:	sdm:ActivityRef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:SegmentDef/ sdm:ActivityRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	ActivityOID, OrderNumber
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
ActivityOID	Required	text	Unique identifier.
OrderName	Required	integer	Display order of the Activity.

5.3.3.2.1.6.5 sdm:ActivityDef Element

An Activity represents a point in a study at which a specific action is to be taken, including data collection activities.

Element Name:	sdm:ActivityDef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:ActivityDef
Element Textual Value:	*None*

Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name
Child Elements:	FormRef

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Short name for the activity.

5.3.3.2.1.6.5.1 Example of Activities that Involve Data Collection

```
<sdm:ActivityDef Name="trial start activity" OID="ACT.TRIALSTART">
   <FormRef FormOID="FO.INCLUSIONEXCLUSION" Mandatory="Yes" />
</sdm:ActivityDef>
<sdm:ActivityDef Name="informed consent activity" OID="ACT.INFORMEDCONSENT">
   <FormRef FormOID="FO.INFORMEDCONSENT" Mandatory="Yes" />
</sdm:ActivityDef>
```

5.3.3.2.1.6.5.2 FormRef Element

Element Name:	FormRef
Element XPath:	/ODM/Study/MetaDataVersion/Protocol/sdm:Structure/sdm:ActivityDef/FormRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	FormOID, Mandatory, OrderNumber
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
FormOID	Required	text	Reference to a FormDef.
Mandatory	Required	"Yes" or "No"	The Mandatory flag indicates that the clinical data for the containing MetaDataVersion would be incomplete without an instance of this type of Form.
OrderNumber	Optional	integer	Display order of the form.

5.3.3.2.2 StudyEventDef Element

A *StudyEventDef* element contains a set of forms.

Element Name:	StudyEventDef
Element XPath:	/ODM/Study/MetaDataVersion/StudyEventDef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name, Repeating, Type, Category
Child Elements:	Description, FormRef, Alias

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the study event. See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Short name for the *StudyEventDef*.
Repeating	Required	"Yes" or "No"	The *Repeating* flag indicates that this type of study event can occur repeatedly.
Type	Required	"Scheduled", "Unscheduled", "Common"	

Attribute	Usage	Allowable Values	Description
Category	Optional	text	The *Category* attribute is typically used to indicate the study phase appropriate to this type of study event. Examples might include Screening, PreTreatment, Treatment, and FollowUp.

5.3.3.2.3 FormDef Element

A FormDef describes a type of form that can occur in a study.

Element Name:	FormDef
Element XPath:	/ODM/Study/MetaDataVersion/FormDef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name, Repeating
Child Elements:	Description, ItemGroupRef, Alias

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the Form. See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Short name for the *FormDef*.
Repeating	Required	"Yes" or "No"	The Repeating flag indicates that this type of form can occur repeatedly within a containing study activity or event.

5.3.3.2.3.1 Example FormDef Element

```
<FormDef Name="ECG Form" OID="FO.ECG" Repeating="No">
   <Description>
      <TranslatedText xml:lang="en">ECG Results</TranslatedText>
   </Description>
   <ItemGroupRef ItemGroupOID="EG" Mandatory="Yes"/>
</FormDef>
```

5.3.3.2.3.2 ItemGroupRef Element

Element Name:	ItemGroupRef
Element XPath:	/ODM/Study/MetaDataVersion/FormDef/ItemGroupRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	ItemGroupOID, OrderNumber, Mandatory
Child Elements :	*None*

Attribute	Usage	Allowable Values	Description
ItemGroupOID	Required	text	A reference to an *ItemGroupDef*.
OrderNumber	Optional	integer	Display order of the ItemGroup within the *FormDef*. Business Rule: If this value is provided for any *ItemGroupRef*, it must be provided for all.
Mandatory	Required	"Yes" or "No"	The Mandatory flag indicates that the clinical data for an instance of the containing form would be incomplete without an instance of this type of item group.

5.3.3.2.4 ItemGroupDef Element

An *ItemGroupDef* describes a type of item group that can occur within a study.

Element Name:	ItemGroupDef
Element XPath:	/ODM/Study/MetaDataVersion/ItemGroupDef
Element Textual Value:	*None*

Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name, Repeating, IsReferenceData, Domain, Purpose, Comment
Child Elements:	Description, ItemRef, Alias

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the Form. See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Short name for the *FormDef*.
Repeating	Required	"Yes" or "No"	The Repeating flag indicates that this type of form can occur repeatedly within a containing study activity or event.
IsReferenceData	Optional	"Yes" or "No"	
Domain	Optional	text	The domain associated with this item group.
Purpose	Optional	text	The *Role* attribute provides a single role name describing the use of this item group.
Comment	Optional	text	

5.3.3.2.4.1 ItemRef Element

Element Name:	ItemRef
Element XPath:	/ODM/Study/MetaDataVersion/ItemGroupDef/ItemRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	ItemOID, OrderNumber, Mandatory, Role, RoleCodeListOID
Child Elements :	*None*

Attribute	Usage	Allowable Values	Description
ItemOID	Required	text	A reference to an *ItemDef*.
OrderNumber	Optional	integer	Display order of the Item within the *ItemGroupDef*. Business Rule: If this value is provided for any *ItemRef*, it must be provided for all.
Mandatory	Required	"Yes" or "No"	The Mandatory flag indicates that the clinical data for an instance of the containing item group would be incomplete without an instance of this type of item.
Role	Optional	text	The *Role* attribute provides a single role name describing the use of this data item.
RoleCodeListID	Optional	text	If the *Role* is defined by a standard terminology, *RoleCodeListOID* may be used to reference a *CodeList* that defines the full set roles from which the *Role* attribute value is to be taken. This attribute should not be present unless the Role attribute is defined. If Role is defined, RoleCodeListOID is still optional.

5.3.3.2.5 ItemDef Element

An *ItemDef* describes a type of item that can occur within a study.

Element Name:	ItemDef
Element XPath:	/ODM/Study/MetaDataVersion/ItemDef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name, DataType, Length, SignificantDigits, Origin, Comment
Child Elements:	Description, CodeListRef, Alias

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the Item. See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Short name for the *ItemDef*.
DataType	Required	"text", "integer", "float", "date", "time" "datetime", "string", "Boolean", "double", "hexBinary", "base64Binary" "hexFloat", "base64Float", "partialDate", "partialTime", "partialDatetime", "durationDatetime", "intervalDatetime", "incompleteDatetime", "incompleteDate", "incompleteTime", "URI"	See section 2.13 Data Formats of the ODM specification for more details on DataTypes.
Length	Conditional Length is required when the DataType is text or string. Length is optional when DataType is integer or float. Length should not be provided for other DataTypes.	positiveInteger	The variable length. Business Rule: Length is defined as the maximum expected variable length. Only be present for DataType equal to "text", "integer", or "float".
SignificantDigits	Conditional Required if DataType is "float".	integer	The number of digits following the decimal point in a floating point number. Business Rule: When *DataType* is float both *Length* and *SignificantDigits* must be provided.
Origin	Optional	text	
Comment	Optional	text	

5.3.3.2.5.1 CodeListRef Element

Element Name:	CodeListRef
Element XPath:	/ODM/Study/MetaDataVersion/ItemDef/CodeListRef
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	CodeListOID
Child Elements :	*None*

Attribute	Usage	Allowable Values	Description
CodeListOID	Optional	text	A reference to a *CodeList* definition. Business Rule: The *DataType* attributes of the referenced *CodeList* and the containing *ItemDef* must be the same.

5.3.3.2.6 CodeList Element

For each Controlled Terminology referenced by variable or ValueList, a CodeList element with the definition of the Controlled terminology must be provided. Use one CodeList element per controlled terminology.

Element Name:	CodeList
Element XPath:	/ODM/Study/MetaDataVersion/CodeList
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or more A CodeList element must be provided for each distinct value of the CodeListOID attribute in a CodeListRef element in the MetaDataVersion.
Attributes:	OID, Name, DataType
Child Elements :	Description, EnumeratedItem, CodeListItem, ExternalCodeList, Alias

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique ID for the CodeList. Refer to Section 3.5.1 "OIDs" See the ODM specification section 2.11 for OID considerations.
Name	Required	text	Name assigned to the CodeList element. In case the CodeList element refers to a subset that is not defined in the referenced Standard Terminology, the value of the Name attribute should correspond to the name assigned to the codelist's subset specifically included in the CTR-XML document.
DataType	Required	Allowable Values: "text", "float", "integer"	The data type of the codes.

5.3.3.2.6.1 EnumeratedItem Element

The EnumeratedItem element defines a CodedValue in a Controlled Terminology. Lists the CodedValues for all items in the controlled terminology.

Element Name:	EnumeratedItem
Element XPath:	/ODM/Study/MetaDataVersion/CodeList/EnumeratedItem
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: • Each CodeList element must contain either one or more EnumeratedItem elements, one or more CodeListItem elements or one ExternalCodelist element. Business Rules: • For Controlled Terminologies, where there is just a list of allowed values, an EnumeratedItem must be provided for each Item included in the Terminology. • The complete set of values relevant to the study must be provided whether or not they are referenced within the study data.
Attributes:	CodedValue, Rank, OrderNumber
Child Elements :	Alias

Attribute	Usage	Allowable Values	Description
CodedValue	Required	text	The coded value. Business Rule: For NCI/CDISC Controlled Terminology, this must exactly match the CodedValue from the published Controlled Terminology ODM.
OrderNumber	Optional	integer	Display order of the item within the CodeList. Business Rule: If this value is provided for any *EnumeratedItem*, it must be provided for all.

5.3.3.2.6.2 CodeListItem Element

The CodeListItem element defines a CodedValue in a Controlled Terminology when a Decode value or Preferred Term is provided for each code. It lists the Coded Values and Decodes for all items in the controlled terminology.

Element Name:	CodeListItem
Element Xpath:	/ODM/Study/MetaDataVersion/CodeList/CodeListItem
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: • Each CodeList element must contain either one or more EnumeratedItem elements, one or more CodeListItem elements or one ExternalCodelist element. Business Rules: • For Controlled Terminologies where there are Coded and Decoded values, a CodeListItem must be provided for each Item included in the Terminology. • The complete set of values relevant to the study must be provided whether or not they are referenced within the study data.
Attributes:	CodedValue, OrderNumber, Rank
Child Elements :	Decode, Alias

Attribute	Usage	Allowable Values	Description
CodedValue	Required	text	The coded value. Business Rule: For NCI/CDISC Controlled Terminology, this must exactly match the CodedValue from the published Controlled Terminology ODM.
OrderNumber	Optional	integer	Display order of the item within the CodeList. Business Rule: If this value is provided for any *CodeListItem*, it must be provided for all.
Rank	Optional	float	The Rank attribute may be used where the relative value corresponding to an enumeration cannot or should not be determined by its lexical order. For example, if you have a list of enumerated text values including "Low", "Medium", and "High" and wish to assign these relative numeric values 1, 2, and 3 respectively, you should include a Rank attribute for each CodeListItem defined. Without the applied rank attribute, the normal lexical ordering would be "High", "Low", and "Medium".

5.3.3.2.6.2.1 Decode Element

The Decode element defines a preferred term for a CodedValue in a CodeListItem.

Element Name:	Decode
Element Xpath:	/ODM/Study/MetaDataVersion/CodeList/CodeListItem/Decode
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: this element is the Container for Decode value, which is provided in the child element TranslatedText.
Attributes:	*None*
Child Elements :	TranslatedText

5.3.3.2.6.3 ExternalCodeList Element

Identifies the source of a 3rd party controlled terminology.

Element Name:	ExternalCodeList
Element Xpath:	/ODM/Study/MetaDataVersion/CodeList/ExternalCodeList
Element Textual Value:	*None*
Usage:	Requirement: Conditional • For Controlled Terminologies provided by 3rd parties, an ExternalCodeList element must be provided to identify the Name and Version of the terminology. Cardinality: 1 • Each CodeList element must contain either one or more EnumeratedItem elements, one or more CodeListItem elements or one ExternalCodelist element. Business Rule: • Required for regulatory submissions to the FDA to provide the reference to the medical dictionaries used.
Attributes:	Dictionary, Version, ref, href
Child Elements :	*None*

Attribute	Usage	Allowable Values	Description
Dictionary	Required	text	The name of the external codelist.
Version	Required	text	The version designator of the external codelist.
Ref	Optional	text	Reference to a local instance of the dictionary.
href	Optional	text	URL of an external instance of the dictionary.

5.3.3.2.7 ConditionDef Element

Element Name:	ConditionDef
Element XPath:	/ODM/Study/MetaDataVersion/ConditionDef
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or more Other Information: A ConditionDef element must be provided for each distinct value of the CodelistOID attribute in a CodeListRef element in the MetaDataVersion.
Attributes:	OID, Name
Child Elements :	Description

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Short name of the condition.

5.3.3.2.8 ctr:Recruitment Element

Element Name:	ctr:Recruitment
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Recruitment
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	ctr:RecruitmentCountries, ctr:RecruitmentStatus

5.3.3.2.8.1 ctr:RecruitmentCountries Element

Element Name:	ctr:RecruitmentCountries
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Recruitment/ctr:RecruitmentCountries
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 Other Information: Container for 1 or more recruitment countries.
Attributes:	*None*
Child Elements:	ctr:RecruitmentCountry

5.3.3.2.8.1.1 ctr:RecruitmentCountry Element

Element Name:	ctr:RecruitmentCountry
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Recruitment/ctr:RecruitmentCountries/ ctr:RecruitmentCountry
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	CountryCode, CodeListOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
CountryCode	Required	Value must be defined in the Codelist referenced by the CodelistOID	
CodeListOID	Required		The referenced Codelist must be defined within this CTR-XML file.

5.3.3.2.8.2 ctr:RecruitmentStatus Element

Element Name:	ctr:RecruitmentStatus
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Recruitment/ctr:RecruitmentStatus
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more Other Information: • There may only be one ctr:RecruitmentStatus element without a Country attribute • The value of the Country attribute must be unique within its series of ctr:RecruitmentStatus elements, i.e. there may not be two ctr:Recruitment elements with the same value of the Country attribute • The value of RecruitmentStartDate may not be later than the value of RecruitmentEndDate • The child element ctr:RecruitmentStatusOther may only be present when the value of the CurrentStatus attribute on the parent ctr:RecruitmentStatus element is "Other"
Attributes:	Country, CurrentStatus, RecrutimentStartDate, RecruitmentEndDate
Child Elements:	ctr:RecruitmentStatusOther

Attribute	Usage	Allowable Values	Description
Country	Conditional	text	Country Code for a RecruitmentCountry defined in the CTR-XML file. If not provided means "worldwide".
CurrentStatus	Required	"Pending", "Recruiting", "Suspended", "Complete", "Other"	
RecruitmentStartDate	Required	partialDate or date	Planned or actual recruitment start date. If the RecruitmentStatus is "Pending" a PartiaDate may be provided. Otherwise it shall be a Date.
RecruitmentEndDate	Optional	partialDate or date	Planned or actual recruitment stop date. If RecruitmentStatus is "Complete" the value shall be a Data. Otherwise a PartialDate may be provided.

5.3.3.2.8.2.1 ctr:RecruitmentStatusOther Element

Element Name:	ctr:RecruitmentStatusOther
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Recruitment/ctr:RecruitmentStatus/ctr:RecruitmentStatusOther
Element Textual Value:	*RecruitmentStatus*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: • Required when the value of the CurrentStatus attribute on the parent ctr:RecruitmentStatus element is "Other". • Shall not be provided for other values of ctr:RecruitmentStatus/CurrentStatus.
Attributes:	*None*
Child Elements:	*None*

5.3.3.2.9 ctr:Interventions Element

Element Name:	ctr:Interventions
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Interventions
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	ctr:Intervention

5.3.3.2.9.1 ctr:Intervention Element

Element Name:	ctr:Intervention
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Interventions/ctr:Intervention
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	OID, InterventionType, Name
Child Elements:	Description, ctr:InterventionOtherName

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
InterventionType	Required	"Behavioral Therapy", "Biologic", "Device", "Dietary Supplement", "Drug", "Genetic", "Other", "Procedure", "Radiation"	

Attribute	Usage	Allowable Values	Description
Name	Required	text	Short name for the intervention. Business Rules: WHO: For drugs use generic name. For other intervention types provide a brief descriptive name. See WHO TRDS for details.

5.3.3.2.9.1.1 ctr:InterventionOtherName Element

The ctr:InterventionOtherName element holds the text name of the other intervention.

Element Name:	ctr:InterventionOtherName
Element XPath:	/ODM/Study/MetaDataVersion/ctr:Interventions/ ctr:Intervention/ctr:InterventionOtherName
Element Textual Value:	*Other name used to identify the intervention.*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	*None*
Child Elements:	*None*

5.3.3.2.10 ctr:OutcomeMeasures Element

Container for one or more ctr:OutcomeMeasure elements.

Element Name:	ctr:OutcomeMeasures
Element XPath:	/ODM/Study/MetaDataVersion/ctr:OutcomeMeasures
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1
Attributes:	*None*
Child Elements:	ctr:OutcomeMeasure

5.3.3.2.10.1 ctr:OutcomeMeasure Element

Element Name:	ctr:OutcomeMeasure
Element XPath:	/ODM/Study/MetaDataVersion/ctr:OutcomeMeasures/ctr:OutcomeMeasure
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	OID, Name, Type, IsSafetyIssue
Child Elements:	Description, ctr:TimePoint

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Short name or title of this outcome measure.
Type	Required	"Primary", "Secondary", "Other"	Business Rules: Only one Primary Outcome should be reported. Any number of Secondary Outcomes or Endpoints may be reported. Use Other for ClinicalTrials.gov element "other prespecified outcome measures.
IsSafetyIssue	Optional	"Yes" or "No"	Yes indicates this outcome is a safety issue.

5.3.3.2.10.1.1 ctr:Timepoint Element

The element *ctr:TimePoint* has a *Description* and an ODM *FormalExpression* element which can be used for providing machine-readable/executable expressions about the time point.

Element Name:	*ctr:Timepoint*
Element XPath:	/ODM/Study/MetaDataVersion/ctr:OutcomeMeasures/ctr:OutcomeMeasure/ctr:Timepoint
Element Textual Value:	*None*
Usage:	Requirement: Required Cardinality: 1 or more
Attributes:	*None*
Child Elements:	Description, FormalExpression

5.3.3.2.10.1.1.1 FormalExpression Element

ODM element for computable FormalExpression.

Element Name:	FormalExpression
Element XPath:	/ODM/Study/MetaDataVersion/ctr:OutcomeMeasures/ctr:OutcomeMeasure/ctr:Timepoint/FormalExpression
Element Textual Value:	FormalExpression
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	*Context*
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Context	Required	text	Application or language to use for evaluating *FormalExpression*.

5.3.3.3 ctr:StudyStartDate Element

Element Name:	ctr:StudyStartDate
Element XPath:	/ODM/Study/ctr:StudyStartDate
Element Textual Value:	date or partialDate value in ISO 8601 format.
Usage:	Requirement: Optional Cardinality: 0 or 1 Business Rules: • Optional for WHO • Required by ClinicalTrials.gov and EudraCT • When the Type is "Anticipated" a partial date is permitted. • When the Type is "Actual" a date is required.
Attributes:	Type
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Type	Required	"Anticipated", "Actual"	Indicates whether this is an actual or anticipated date.

5.3.3.4 ctr:StudyEndDate Element

Element Name:	ctr:StudyEndDate
Element XPath:	/ODM/Study/ctr:StudyEndDate
Element Textual Value:	Date or partialDate value in ISO 8601 format.
Usage:	Requirement: Optional

	Cardinality: 0 or 1 Business Rules: • Maps to Primary Completion Date in ClinicalTrials.gov • In EudraCT, if Type = "Actual" then *Global end of trial reached?* = "Yes" otherwise it is set to "No". • When the Type is "Anticipated" a partial date is permitted. • When the Type is "Actual" a date is required.
Attributes:	Type
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Type	Required	"Anticipated", "Actual"	Indicates whether this is an actual or anticipated date.

5.3.3.5 ctr:StudyEndDatePrimaryOutcome Element

Element Name:	ctr:StudyEndDatePrimaryOutcome
Element XPath:	/ODM/Study/ctr:StudyEndDatePrimaryOutcome
Element Textual Value:	*Date*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: • Required when submitting a interventional trial to ClinicalTrials.gov • When the Type is "Anticipated" a partial date is permitted. • When the Type is "Actual" a date is required.
Attributes:	Type
Child Elements:	None

Attribute	Usage	Allowable Values	Description
Type	Required	"Anticipated", "Actual"	Indicates whether this is an actual or anticipated date.

5.3.3.6 ct:medicinal_product_information Element

The *ct:medicinal_product_information* element is required for EudraCT submissions. The CTR-XML standard includes a subset of EudraCT XML-Schemas (v.10), and those elements are indicated by the *ct:* prefix in this specification. Only the required child elements are listed below due to the large number of possible elements. Detailed descriptions for each child element are not included in this specification, but may be found at https://eudract.ema.europa.eu/protocol.html. This web site provides the schemas and data dictionary describing each of the child elements, including the optional ones not included in this specification.

Element Name:	ct:medicinal_product_information
Element XPath:	/ODM/Study/ct:medicinal_product_information
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:medicinal_product

5.3.3.6.1 ct:medicinal_product Element

Element Name:	ct:medicinal_product
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or more

	Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:imp_category, ct:has_ma, ct:imp_member_state, ct:imp_identification_not_possible, ct:has_full_impd, ct:has_simplified_impd, ct:has_summary_of_prod_character, ct:is_prev_auth_in_community, ct:member_states, ct:is_orphan_drug_in_community, ct:orphan_drug_designation_no, ct:has_scientific_advice, ct:has_scientific_advice_chmp, ct:has_scientific_advice_nca, ct:name, ct:code, ct:atc_codes, ct:pharmaceutical_form, ct:is_paediatric_formulation, ct:first_dose_fih_total_dose_unitct:max_duration_imp, ct:first_dose_fih_allowed, ct:first_dose_fih_per_day_total, ct:max_dose_imp, ct:first_dose_fih_total_dose_num, ct:first_dose_fih_roa, ct:max_dose_perday_total_imp, ct:total_dose_number, ct:total_dose_unit, ct:max_dose_route_of_administration, ct:routes_of_administration, ct:has_chemical_origin, ct:has_biological_origin, ct:is_advanced_therapy_mp, ct:is_somatic_therapy_mp, ct:is_gene_therapy_mp, ct:is_tissue_engineered_mp, ct:is_combination_atimp, ct:is_cat_classification_isued, ct:cat_classification, ct:is_device_included, ct:is_plasma_derived_mp, ct:is_radiopharmaceutical_mp, ct:is_immunological_mp, ct:is_genetically_mod_auth_accord, ct:is_other_extractive, ct:is_recombinant_mp, ct:is_gmo_mp, ct:is_genetically_mod_auth_pend, ct:is_herbal_mp, ct:is_homeopathetic_mp, ct:is_other_mp, ct:other_mp_specification, ct:mode_of_action, ct:is_first_in_human, ct:first_in_human_risk_factors, ct:somatic_cell, ct:gene_therapy, ct:cell_origin, ct:cell_type, ct:imp_device, ct:active_substances

5.3.3.6.1.1.1 ct:eutct_id Element

Element Name:	ct:eutct_id
Element XPath(s):	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:imp_category/ ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:imp_member_state/ct:granted_ma_country/ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:pharmaceutical_form/ ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:first_dose_fih_total_dose_unit/ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:first_dose_fih_roa/ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:total_dose_unit/ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:max_dose_route_of_administration/ct:eutct_id /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:imp_member_state/ct:granted_ma_country/ ct:eutct_id
Element Textual Value:	Positive integer
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	*None*

5.3.3.6.1.1.2 ct:eutct_version Element

Element Name:	ct:eutct_version
Element XPath(s):	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:imp_category/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:imp_member_state/ct:granted_ma_country/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:pharmaceutical_form/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:first_dose_fih_total_dose_unit/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:first_dose_fih_roa/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:total_dose_unit/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:max_dose_route_of_administration/ct:eutct_version /ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:imp_member_state/ct:granted_ma_country/ct:eutct_version
Element Textual Value:	Positive integer
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	*None*

5.3.3.6.1.2 ct:imp_member_state Element

Element Name:	ct:imp_member_state
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:imp_member_state
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:trade_name_in_ms, ct:ev_identifiable_product_code, ct:ma_holder, ct:ma_number, ct:is_imp_modified, ct:imp_modified_specification, ct:granted_ma_country, ct:is_granting_ma_concerned_ms

5.3.3.6.1.3 ct:imp_identification_not_possible Element

Element Name:	ct:imp_identification_not_possible
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ct:imp_identification_not_possible
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Business Rules: Required for EudraCT submissions.
Attributes:	None
Child Elements:	ct:has_any_auth_active_substance, ct:has_local_site_products, ct:is_atc_group_used, ct:has_imp_other_identification, ct:other_description

5.3.3.6.1.4 ct:somatic_cell Element

Element Name:	ct:somatic_cell
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:somatic_cell
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:somatic_cell_autologous, ct:somatic_cell_allogeneic, ct:somatic_cell_xenogeneic, ct:somatic_cell_xen_sp_origin, ct:somatic_cell_stem, ct:somatic_cell_differenciated, ct:somatic_cell_diff_type, ct:somatic_cell_others, ct:somatic_cell_others_specify

5.3.3.6.1.5 ct:gene_therapy Element

Element Name:	ct:gene_therapy
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:gene_therapy
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:gene_ther_genes_of_interest, ct:gene_ther_in_vivo, ct:gene_ther_ex_vivo, ct:gene_ther_nucleic_acid, ct:gene_ther_nucleic_acid_naked, ct:gene_ther_nucleic_acid_complex, ct:gene_ther_viral, ct:gene_ther_viral_specify, ct:gene_ther_others, ct:gene_ther_others_specify, ct:gene_ther_genetically_modified, ct:gene_ther_autologous, ct:gene_ther_allogeneic, ct:gene_ther_xenogeneic, ct:gene_ther_xeno_species_origin, ct:gene_ther_type_cells_dtls

5.3.3.6.1.6 ct:cell_origin Element

Element Name:	*ct:cell_origin*
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:cell_origin
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:tissue_eng_origin_autologous, ct:tissue_eng_origin_allogeneic, ct:tissue_eng_origin_xenogeneic, ct:tissue_eng_xenogeneic_species

5.3.3.6.1.7 ct:cell_type Element

Element Name:	ct:cell_type
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:cell_type
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.

Attributes:	*None*
Child Elements:	ct:tissue_eng_type_stem, ct:tissue_eng_type_differentiated, ct:tissue_eng_diff_spec, ct:tissue_eng_other, ct:tissue_eng_other_spec

5.3.3.6.1.8 ct:imp_device Element

Element Name:	ct:imp_device
Element XPath:	/ODM/Study/ct:medicinal_product_information/ct:medicinal_product/ ct:imp_device
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:device_description, ct:device_name, ct:device_implantable, ct:is_medical_device, ct:has_device_ce_mark, ct:device_notified_body, ct:has_biomedical_material, ct:has_scaffolds, ct:has_matrices, ct:has_other_device, ct:other_device_spec

5.3.3.7 ct:population_information Element

The *ct:population_information* element is required for EudraCT submissions. The CTR-XML standard includes a subset of EudraCT XML-Schemas (v.10), and those elements are indicated by the ct: prefix in this specification. Only the required child elements are listed below due to the large number of possible elements. Detailed descriptions for each child element are not included in this specification, but may be found at https://eudract.ema.europa.eu/protocol.html. This web site provides the schemas and data dictionary describing each of the child elements, including the optional ones not included in this specification.

Element Name:	*ct:population_information*
Element XPath:	/ODM/Study/ct:population_information
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1 Other Information: Required for EudraCT submissions.
Attributes:	*None*
Child Elements:	ct:has_under_18, ct:under_18_subjects_no, ct:has_in_utero, ct:in_utero_no, ct:has_preterm_newborn_infants, ct:preterm_newborn_infants_no, ct:has_newborns, ct:newborns_no, ct:has_infants_and_toddlers, ct:infants_and_toddlers_no, ct:has_childen, ct:childen_no, ct:has_adolescents, ct:adolescents_no, ct:has_adults, ct:adults_no, ct:has_elderly, ct:elderly_no, ct:is_gender_male, ct:is_gender_female, ct:has_healthy_volunteers, ct:has_patients, ct:has_specific_vunerable_popul, ct:has_women_child_bear_contra, ct:has_women_child_bear_potent, ct:has_pregnant_women, ct:has_nursing_women, ct:has_emergency_situation, ct:has_incapable_consent, ct:has_incapable_consent_details_localized, ct:has_other_patient, ct:other_patient_details_localized, ct:in_ms_no, ct:in_eea_no, ct:in_whole_trial, ct:post_trial_treatment_details_localized,

5.3.4 AdminData Element

Container for User elements.

Element Name:	AdminData
Element XPath:	/ODM/AdminData
Element Textual Value:	*None*
Usage:	Requirement: Conditional Cardinality: 0 or 1
Attributes:	StudyOID
Child Elements:	User, ctr:Organization

Attribute	Usage	Allowable Values	Description
StudyOID	Optional	text	Reference to a Study element.

5.3.4.1 User Element

Element Name:	User
Element XPath:	/ODM/AdminData/User
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, UserType
Child Elements:	DisplayName, FullName, Organization, Address, Email, ctr:Role, ctr:Qualifications, ctr:OrganizationRef

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
UserType	Optional	"Sponsor", "Investigator", "Lab", "Other"	

5.3.4.1.1 DisplayName Element

A short displayable name for the user.

Element Name:	*FullName*
Element XPath:	/ODM/AdminData/User/FullName
Element Textual Value:	*User's display name*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.2 FullName Element

The user's full formal name.

Element Name:	*FullName*
Element XPath:	/ODM/AdminData/User/FullName
Element Textual Value:	*User's full name*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.3 Organization Element

The user's organization.

Element Name:	*Organization*
Element XPath:	/ODM/AdminData/User/Organization
Element Textual Value:	*User's organization*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.4 Email Element

The user's email address.

Element Name:	Email
Element XPath:	/ODM/AdminData/User/Email
Element Textual Value:	User's email address
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.5 ctr:Role Element

Element Name:	ctr:Role
Element XPath:	/ODM/AdminData/User/ctr:Role /ODM/AdminData/User/ctr:Organization/ctr:Role
Element Textual Value:	The name of the user's role
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	Context, RoleCodeListOID
Child Elements:	*None*

Attribute	Usage	Allowable Values	Description
Context	Required	text	Unique identifier.
RoleCodeListOID	Conditional Required for EudraCT submissions	OID of a CodeList containing the possible roles	Reference to a CodeList of roles.

5.3.4.1.6 ctr:Qualifications Element

Element Name:	ctr:Qualifications
Element XPath:	/ODM/AdminData/User/ctr:Qualifications
Element Textual Value:	The investigator's qualifications
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7 ctr:Organization Element

Element Name:	ctr:Organization
Element XPath:	/ODM/AdminData/User/ctr:Organization
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	OID, Name
Child Elements:	Address, Email, Fax, Certificate, ctr:Role

Attribute	Usage	Allowable Values	Description
OID	Required	text	Unique identifier.
Name	Required	text	Name for the organization.

5.3.4.1.7.1 Address Element

Element Name:	Address
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address
Element Textual Value:	The user's postal address
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	*None*
Child Elements:	StreetName, City, StateProv, Country, PostalCode, OtherText

5.3.4.1.7.1.1 StreetName Element

Element Name:	StreetName
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/StreetName
Element Textual Value:	The street address part of a user's postal address
Usage:	Requirement: Optional Cardinality: 0 or more
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.1.2 City Element

Element Name:	City
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/City
Element Textual Value:	The city name part of a user's postal address
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.1.3 StateProv Element

Element Name:	StateProv
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/StateProv
Element Textual Value:	The state or province part of a user's postal address
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.1.4 Country Element

Element Name:	*Country*
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/Country
Element Textual Value:	*The country name part of a user's postal address.*
Usage:	Requirement: Optional Cardinality: 0 or 1 Other Information: *Country must be represented by an ISO 3166 two-letter country code (e.g. FR for France, JP for Japan)*
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.1.5 PostalCode Element

Element Name:	*PostalCode*
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/PostalCode

Element Textual Value:	*The postal code part of a user's postal address.*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.1.6 OtherText Element

Element Name:	*OtherText*
Element XPath:	/ODM/AdminData/User/ctr:Organization/Address/OtherText
Element Textual Value:	*Any other text needed as part of a user's postal address.*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.2 Fax Element

Element Name:	*Fax*
Element XPath:	/ODM/AdminData/User/ctr:Organization/Fax
Element Textual Value:	*The phone number of the user's facsimile machine.*
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	*None*
Child Elements:	*None*

5.3.4.1.7.3 Certificate Element

Element Name:	*Certificate*
Element XPath:	/ODM/AdminData/User/ctr:Organization/Certificate
Element Textual Value:	*The user's digital signing certificate.*
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	*None*
Child Elements:	*None*

5.3.4.2 ctr:CentralTechnicalFacilities Element

Element Name:	ctr:CentralTechnicalFacilities
Element XPath:	/ODM/AdminData/ctr:CentralTechnicalFacilities
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	None
Child Elements:	ctr:CentralTechnicalFacility

5.3.4.2.1 ctr:CentralTechnicalFacility Element

Central Technical Facilities includes central laboratories and central ECG or image processing facilities.

Element Name:	ctr:CentralTechnicalFacility
Element XPath:	/ODM/AdminData/ctr:CentralTechnicalFacilities/ctr:CentralTechnicalFacility
Element Textual Value:	None
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	None
Child Elements:	ctr:OrganizationRef, ctr:Contact, ctr:CentralTechnicalFacilityDuty

5.3.4.2.1.1 ctr:CentralTechnicalFacilityDuty Element

The details of any duties subcontracted to this central technical facility for this trial.

Element Name:	ctr:CentralTechnicalFacility
Element XPath:	/ODM/AdminData/ctr:CentralTechnicalFacilities/ ctr:CentralTechnicalFacility/ctr:CentralTechnicalFacilityDuty
Element Textual Value:	Text description of duty from enumerated values in Section 4.3.3.3`
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	CodeListOID
Child Elements:	None

Attribute	Usage	Allowable Values	Description
CodeListOID	Required	text See enumerated terms in Section 4.3.3.3	References a *Codelist* within the *MetaDataVersion* element. An ODM *Codelist* must be provided with the enumerated values for CentralTechnicalFacilityDuty in Section 4.3.3.3. Roles.

5.3.4.3 ctr:Networks Element

Element Name:	ctr:Networks
Element XPath:	/ODM/AdminData/ctr:Networks
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1
Attributes:	None
Child Elements:	ctr:Network

5.3.4.3.1 ctr:Network Element

The details of any clinical investigator network involved in the clinical trial.

Element Name:	ctr:Network
Element XPath:	/ODM/AdminData/ctr:Neworks/ctr:CentralNetwork
Element Textual Value:	None
Usage:	Requirement: Optional Cardinality: 1 or More
Attributes:	None
Child Elements:	ctr:OrganizationRef, ctr:Contact, ctr:NetworkActivities

5.3.4.3.1.1 ctr:NetworkActivities Element

Description of the activities performed by the network.

Element Name:	ctr:NetworkActivities
Element XPath:	/ODM/AdminData/ctr:Neworks/ctr:CentralNetwork/ctr:NetworkActivities
Element Textual Value:	Text description of activities carried out by the network
Usage:	Requirement: Optional Cardinality: 1 or More
Attributes:	None
Child Elements:	None

5.3.4.4 ctr:SubContractors Element

Element Name:	ctr:SubContractors
Element XPath:	/ODM/AdminData/ctr:SubContractors
Element Textual Value:	*None*
Usage:	Requirement: Optional Cardinality: 0 or 1

Attributes:	None
Child Elements:	ctr:SubContractor

5.3.4.4.1 ctr:SubContractor Element

The details of any organization to whom the sponsor has transferred trial related duties and functions.

Element Name:	ctr:SubContractor
Element XPath:	/ODM/AdminData/ctr:SubContractors/ctr:SubContractor
Element Textual Value:	None
Usage:	Requirement: Optional Cardinality: 1 or More
Attributes:	None
Child Elements:	ctr:OrganizationRef, ctr:Contact, ctr:SubContractorDuty

5.3.4.4.1.1 ctr:SubContractorDuty Element

Description of any duties/functions subcontracted to the sponsor's subcontractor facility in this trial.

Element Name:	ctr:SubContractorDuty
Element XPath:	/ODM/AdminData/ctr:SubContractors/ctr:SubContractor/ ctr:SubContractorDuty
Element Textual Value:	Text description duties/functions of the subcontractor
Usage:	Requirement: Optional Cardinality: 0 or More
Attributes:	CodeListOID
Child Elements:	None

Attribute	Usage	Allowable Values	Description
CodeListOID	Required	text	References a *Codelist* within the *MetaDataVersion* element. An ODM *Codelist* must be provided with the enumerated values for SubContractorDuty.

6 ODM Changes and Extensions Supporting CTR-XML

Element / Attribute	Description
ODM/@ctr:CTRXMLVersion	An extension attribute to capture the version of the CTR-XML standard has been added as part of the CTR-XML ODM extension.

Appendices

Appendix A: Acknowledgments

This specification was developed by the CDISC CTR-XML Development Team, a sub-team of the CDISC XML Technologies Team:

Jozef Aerts, University of Applied Sciences FH Joanneum, Graz
Sally Cassells, Next Step Clinical Systems LLC
Sam Hume, Next Step Clinical Systems LLC

Appendix B: Trial Summary Parameters that Must be Included for Submission to a Clinical Trial Registry

The following trial summary parameters from the CDISC controlled terminology TSPARMCD / TSPARM codelist **must** be included in the *sdm:Summary* section of the ODM file as an *sdm:Parameter*.

For example:

```
<sdm:Parameter OID="PAR.OBJPRIM" ShortName="OBJPRIM"
     Term="Trial primary objective">
   <sdm:Value>To determine if there is a statistically significant relationship
        between the change in both ADAS-Cog and CIBIC+ scores, and drug dose (0,
        50 cm2 [54 mg], and 75 cm2 [81 mg])</sdm:Value>
   <sdm:Value>To document the safety profile of the xanomeline TTS.</sdm:Value>
</sdm:Parameter>
```

Please be aware that the value of the OID is always arbitrary, the value of "ShortName" is leading.

ShortName	Term	Comments / Remarks
OBJPRIM	Trial Primary Objective	
OBJSEC	Trial Secondary Objective	
OUTMSEXP	Exploratory Outcome Measure	
OUTMSPRI	Primary Outcome Measure	
OUTMSSEC	Secondary Outcome Measure	
PLANSUB	Planned Number of Subjects	
RANDOM	Trial is Randomized	
STYPE	Study Type	
INTMODEL	Intervention Model	
TPHASE	Trial Phase	
INDIC	Trial Indication	
TCNTRL	Control Type	
TTYPE	Trial Type	
TITLE	Trial Title	
HLTSUBJI	Healthy Subject Indicator	
INTTYPE	Intervention Type	
THERAREA	Therapeutic Area	Term requested to CDISC-CT team

Others may be required in the scope of EudraCT (see Section 1.3.2 for EutraCT specific information) or in the scope of ClinicalTrials.gov (see section ClinicalTrials.gov specific elements).

Appendix C: XML Schema

The examples in this document are included in XML files as part of the CTR-XML 1.0 publication. These XML files reference (directly or indirectly) the following schema files:

CTR-XML schema	schema/ctr1-0-0.xsd
	schema/ctr-extension.xsd
	schema/ctr-ns.xsd
	schema/ctr-sdm-extension.xsd
EudraCT-XML schema	schema/eudract-ns.xsd
	schema/eudract-ns.xsd
	schema/EudraCT_v10/medicinal_product_information.xsd
	schema/EudraCT_v10/population_information.xsd
SDM-XML schema	schema/sdm1-0-0.xsd
	schema/sdm-ns.xsd
	schema/sdm-ns-common.xsd
	schema/sdm-ns-structure.xsd
	schema/sdm-ns-timing.xsd
	schema/sdm-ns-workflow.xsd
ODM 1-3-2 schema	schema/cdisc-odm-1.3.2/ODM1-3-2.xsd
	schema/cdisc-odm-1.3.2/ODM1-3-2-foundation.xsd
	schema/cdisc-odm-1.3.2/xlink.xsd
	schema/cdisc-odm-1.3.2/xml.xsd
	schema/cdisc-odm-1.3.2/xmldsig-core-schema.xsd

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