ODM v2.0: Public Review

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Agenda

1. Introduction to ODM v2.0
2. ODM v2.0 Timelines
3. New ODM v2.0 Feature Highlights

Introduction to ODM v2.0

The Operational Data Model and its Extensions

ODM Background

- The Operational Data Model (ODM) is the CDISC Data Exchange Standard
- Numerous data exchange standards developed as ODM extensions
  - Example: Define-XML
  - Many more proprietary extensions have been developed
- ODM v1.x is > 20 years old
  - Previous version, ODM v1.3.2, was published in 2013
- ODM v2.0 is a major new version that modernizes ODM and builds on its strengths
  - Breaks backwards compatibility with ODM v1.3.2
- ODM is the most widely implemented CDISC standard

ODM Use Cases

- Automated set up of EDC / CDM systems
- Data transmission from 3rd party data providers to sponsors
- Clinical data archiving
- Data lakes
- Clinical data standards metadata repositories
- Electronic Health Record integration
- Study design representation and automation

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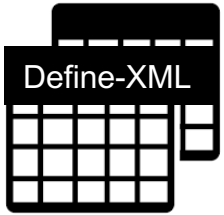
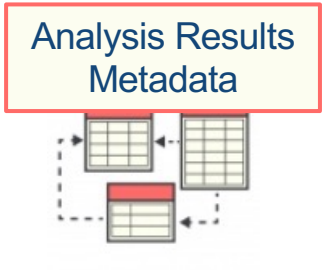
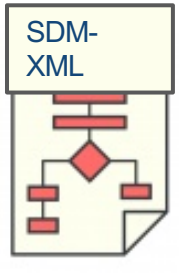
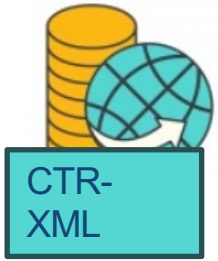
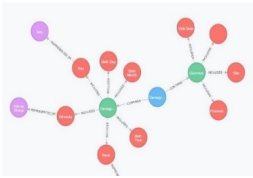
ODM-based Data Exchange Standards











Trace-XML

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ODM v2.0 Objectives

- Consolidate extensions into the base ODM standard
- Address gaps in transport coverage and expand automation opportunities
  - E.g. Study design, API, JSON, tabular data exchange
- Robust semantics – strengthen semantic representations
- Improve alignment with foundational standards and RWD
- Flexible data structures that go beyond CRF representation
- Support for regulations and research specific content
  - E.g. Audit trails, Data Queries

ODM v2.0 Timelines

Estimated timelines towards a final standard

ODM v2.0 Status and Timelines

- Internal Review ended August 30th 2022
- COSA Dataset-JSON Hackathon completed October 19th 2022
- Public Review targeted for November 8th – January 31st
- Public Review Webinar on January 12th 2023
- Final release targeted for Q2 2023
- Some features that are not part of the base specification will come out later, such as:
  - Conformance rules, the API specification, JSON schemas, ODMPath, and additional examples

ODM v2.0 Public Review References

- ODM v2.0 Public Review Notice:
  - https://www.cdisc.org/public-review/odm-v2-0
- Draft Specification for Review:
  - https://wiki.cdisc.org/display/ODM2/Operational+Data+Model+v2+Home
- Instructions for Reviewers:
  - https://wiki.cdisc.org/display/ODM2/Instructions+for+Reviewers
- ODM v2.0 Review Comments:
  - https://jira.cdisc.org/projects/ODM
- ODM v2.0 schema in GitHub:
  - https://github.com/cdisc-org/DataExchange-ODM
- ODM v2.0 Changes from the Previous Version:
  - https://wiki.cdisc.org/pages/viewpage.action?pageId=159332369

Tasks Planned for During Public Review

- **ODM-13 Reorganization of Page notes** (Public Review)

Discussed to move notes currently at the bottom of Specification pages to the Element or Attributes tables as may correspond. To start with notes that are clear Business Rules or Conditionality requirements that fit on the Element or Attributes tables.

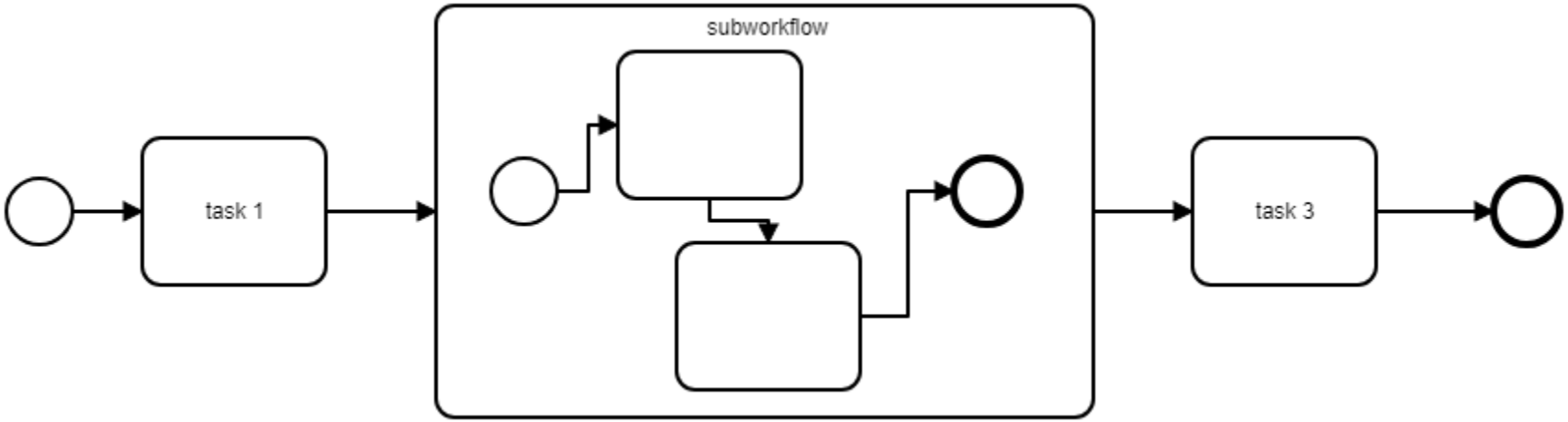
- **ODM-49 Look into representing default values and CDASH attributes** (Public Review)

We had an eCRF Portal meeting last week with Peter and I have an action that involves ODM v2. How can I find out if items we have stored in alias right now will have fields in ODM v2? CDASH Variable, Prefill value, CRF Completion Instructions. Look into library-xml.

New ODM v2.0 Feature Highlights

What new features have been added to ODM v2.0?

Study Design and Workflow



In addition to Study Design, added nested StudyEventGroupDef

https://wiki.cdisc.org/display/ODM2/Study+Design+Model+Elements+in+ODM

JSON Representation

```
"Protocol": {
    "StudyEventRef": [{
        "Mandatory": "Yes",
        "OrderNumber": 1,
        "StudyEventOID": "BASELINE"
    }]
}
```

https://wiki.cdisc.org/display/ODM2/JSON++representation++for++ODM

Coding Element

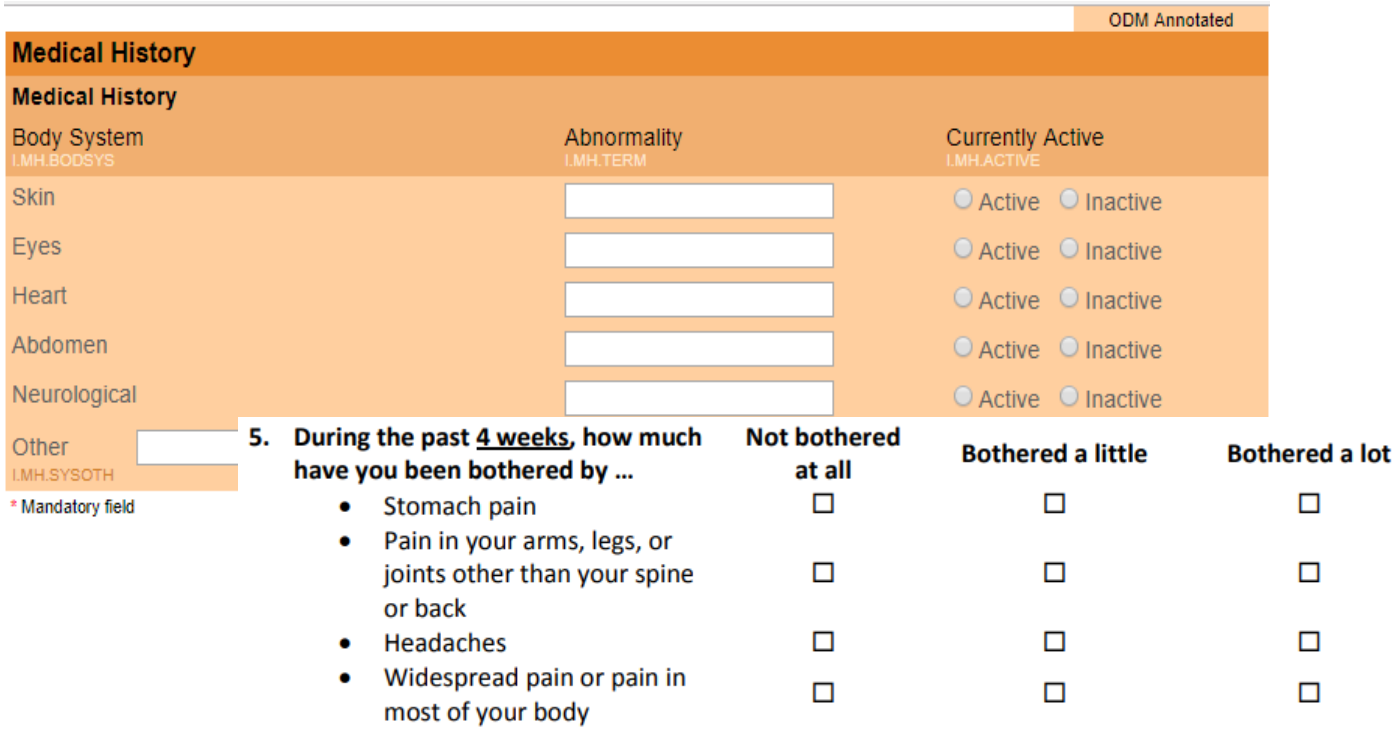
```
<Coding Code="C78802"
        System="https://www.cdisc.org/standards/terminology"
        SystemName="CDISC/NCI CT"
        SystemVersion="2019-12-20"
/>

<Coding Code="394844007"
        System="http://snomed.info/sct"
        SystemName="SNOMED-CT"
        SystemVersion="2019.10.03"
/>
```

Dynamic Data Structures

```
<ItemGroupDef OID="ODM.IG.LB" Name="LAB Measurements" Repeating="No" Type="Form">
    <ItemRef ItemOID="ODM.IT.LB.LBDTC" Mandatory="Yes"/>
    <ItemGroupRef ItemGroupOID="ODM.IG.LB.WBC" Mandatory="Yes"/>
    <ItemRef ItemOID="ODM.IT.LB.ALB.LBORRES" Mandatory="Yes"/>
    <ItemRef ItemOID="ODM.IT.LB.ALB.LBORRESU" Mandatory="Yes"/>
    <ItemRef ItemOID="ODM.IT.LB.GLUC.LBORRES" Mandatory="Yes"/>
    <ItemRef ItemOID="ODM.IT.LB.GLUC.LBORRESU" Mandatory="Yes"/>
</ItemGroupDef>
```

https://wiki.cdisc.org/display/ODM2/ItemGroupDef

Enhanced Data Capture



ODM Annotated

Medical History

Medical History

Body System I.MH.BODSYS	Abnormality I.MH.TERM	Currently Active I.MH.ACTIVE
Skin		Active Inactive
Eyes		Active Inactive
Heart		Active Inactive
Abdomen		Active Inactive
Neurological		Active Inactive
Other I.MH.SYSOTH		

* Mandatory field

5. During the past 4 weeks, how much have you been bothered by …	Not bothered at all	Bothered a little	Bothered a lot
• Stomach pain	☐	☐	☐
• Pain in your arms, legs, or joints other than your spine or back	☐	☐	☐
• Headaches	☐	☐	☐
• Widespread pain or pain in most of your body	☐	☐	☐

https://wiki.cdisc.org/display/ODM2/ItemGroupDef

HL7 FHIR Interoperability

```
<ItemGroupDef OID="ODM.IG.LB.WBC" Name="WBC Lab Results with Unit" Repeating="No" Type="Form" MethodOID="ODM.MT.LB.LBORRES">
    <ItemRef ItemOID="ODM.IT.LB.WBC.LBORRES" Mandatory="Yes"/>
    <ItemRef ItemOID="ODM.IT.LB.WBC.LBORRESU" Mandatory="Yes"/>

    <Origin Type="EHR" Source="Investigator">
        <Description>
            <TranslatedText xml:lang="en">Lab values retrieved from EHR using FHIR</TranslatedText>
        </Description>
        <Source>
            <SourceItem>
                <Resource Type="HL7-FHIR" Name="Observation" Attribute="valueQuantity.value">
                    <Selection Path="Resource/@Name='Observation' and Resource/@Attribute='valueQuantity.value"/>
                </Resource>
            </SourceItem>
            <SourceItem>
                <Resource Name="Observation" Attribute="valueQuantity.unit" Label="unit">
                    <Selection Path="Resource/@Name='Observation' and Resource/@Attribute='valueQuantity.unit"/>
                </Resource>
            </SourceItem>
            <Coding Code="26464-8" System="http://loinc.org" SystemName="LOINC" SystemVersion="2.61" Label="loinc_code"/>
        </Source>
    </Origin>
</ItemGroupDef>
```

FHIR Resource

LOINC Code

https://wiki.cdisc.org/display/ODM2/Origin

Enhanced Traceability

StudyDesign: Demographics (DM_1) [DM_UseCase1]

Demographics [DM_UseCase1]

1.*	Birth Date [Birth Date]	[BRTHDAT] [BRTHYR] Birth Year Req (2012-2014) [BRTHMO] Birth Month NReq
2.*	Sex [Sex]	[SEX] [A:F] Female [A:M] Male
3.*	Ethnicity [Ethnicity]	[ETHNIC] [A:HISPANIC OR LATINO] Hispanic or Latino [A:NOT HISPANIC OR LATINO] Not Hispanic or Latino [A:NOT REPORTED] Not reported [A:UNKNOWN] Unknown
4.*	Race [Race]	[RACE] [A:AMERICAN INDIAN OR ALASKA NATIVE] American Indian or Alaska Native [A:ASIAN] Asian [A:BLACK OR AFRICAN AMERICAN] Black or African American [A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] Native Hawaiian or Other Pacific Islander [A:WHITE] White

Key: [*] = Item is required

CDASH ODM

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICTTC	RFPENDTC
1	ABC123	DM	ABC12301001	001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01
2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26
3	ABC123	DM	ABC12301003	003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19
4	ABC123	DM	ABC12301004	004					2006-01-07	2006-01-08
5	ABC123	DM	ABC12302001	001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12
6	ABC123	DM	ABC12302002	002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25

Row	SITEID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC
		JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC
		JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC
		JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC
4 (cont)	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO
5 (cont)	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO
6 (cont)	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO

Row	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY
1 (cont)	A	Drug A	A	Drug A	USA
2 (cont)	P	Placebo	P	Placebo	USA
3 (cont)	P	Placebo	P	Placebo	USA
4 (cont)	SCRNFAIL	Screen Failure	SCRNFAIL	Screen Failure	USA
5 (cont)	P	Placebo	P	Placebo	USA
6 (cont)	A	Drug A	A	Drug A	USA

SDTM Define-XML

Row	PARAM	AVISIT	AVISITN	VISITNUM	VSSEQ	ABLFL	AVAL	BASE	CHG	PARAMTYP	DTYPE
1	Weight (kg)	Screening	-4	1	1164		99	100	.		
2	Weight (kg)	Run-In	-2	2	1165		101	100	.		
3	Weight (kg)	Baseline	0	3	1166	Y	100	100	0		
4	Weight (kg)	Week 24	24	4	1167		94	100	-6		
5	Weight (kg)	Week 48	48	5	1168		92	100	-8		
6	Weight (kg)	Week 52	52	6	1169		95	100	-5		
		Endpoint	9999				93.5	100	-6.5		AVERAGE
	kg)	Screening	-4	1	1164		1.9956	2	.	DERIVED	
	kg)	Run-In	-2	2	1165		2.0043	2	.	DERIVED	
10	Log10(Weight (kg))	Baseline	0	3	1166	Y	2	2	0	DERIVED	
11	Log10(Weight (kg))	Week 24	24	4	1167		1.9731	2	-0.0269	DERIVED	
12	Log10(Weight (kg))	Week 48	48	5	1168		1.9638	2	-0.0362	DERIVED	
13	Log10(Weight (kg))	Week 52	52	6	1169		1.9777	2	-0.0223	DERIVED	
14	Log10(Weight (kg))	Endpoint	9999				1.9708	2	-0.0292	DERIVED	AVERAGE

ADaM Define-XML

Enhanced MethodDef

```
<MethodDef OID="ODM.MT.LB.LBORRES" Name="Retrieve Lab Result using FHIR" Type="Preload">
    <Description>
        <TranslatedText xml:lang="en" type="text/plain">FHIR API call definition to retrieve lab result</TranslatedText>
    </Description>
    <MethodSignature>
        <Parameter Name="value" Definition="Lab Result" DataType="text"/>
        <Parameter Name="unit" Definition="Result Unit" DataType="text"/>
        <Parameter Name="loinc_code" Definition="LOINC Code" DataType="text"/>
        <ReturnValue Name="LBORRES" Definition="Lab result from the EHR system" DataType="text"/>
        <ReturnValue Name="LBORRESU" Definition="Lab result from the EHR system" DataType="text"/>
    </MethodSignature>
    <FormalExpression Context="Python 3.7">
        <!-- assumes have access to study state (e.g. subjectid, studyid, etc) and can retrieve patient_id using ResearchSubject -->
        <!-- assumes libraries have been imported: "from fhirclient import client" and "import fhirclient.models.observation as ob" -->
        <Code>
            smart = client.FHIRClient(settings={'app_id': 'rof_adapter', 'api_base': 'https://api.logicahealth.org/STU301withSynthea/open'})
            search_obs = ob.Observation.where(struct=dict(patient=patient_id, code=loinc_code))
            value = ""
            unit = ""
            if search_obs.perform_resources(smart.server):
                obs = search_obs.perform_resources(smart.server).pop().as_json()
                value = obs["valueQuantity"]["value"]
                unit = obs["valueQuantity"]["unit"]
            return value, unit
        </Code>
    </FormalExpression>
</MethodDef>
```

Presentation: Formatted Text

@type="text/plain"

@type="application/xhtml+xml"

```
<Description>
    <TranslatedText xml:lang="en" type="text/plain">Study Day Derivation
        Study day (ADY) is derived differently for events occurring:
        Before the first dose date.
        On or after the first dose date.
        When the event date (ADT) is before the first dose date (TRTSDT):
        ADY = ADT - TRTSTDT.
        When the event date (ADT) is on or after the first dose date (TRTSDT):
        ADY = ADT - TRTSTDT + 1.
    </TranslatedText>
    <TranslatedText xml:lang="en" type="application/xhtml+xml">
        <div xmlns="https://www.w3.org/1999/xhtml/">
            <h3>Study Day Derivation</h3>
            <p><strong>Study day</strong> (ADY) is derived differently for events occurring:</p>
            <ol>
                <li>Before the first dose date.</li>
                <li>On or after the first dose date.</li>
            </ol>
            <p>When the event date (<em>ADT</em>) is before the first dose date (<em>TRTSDT</em>):</p>
            <p><code>ADY = ADT - TRTSTDT.</code></p>
            <p>When the event date (<em>ADT</em>) is on or after the first dose date (<em>TRTSDT</em>):</p>
            <p><code>ADY = ADT - TRTSTDT + 1.</code></p>
        </div>
    </TranslatedText>
</Description>
```

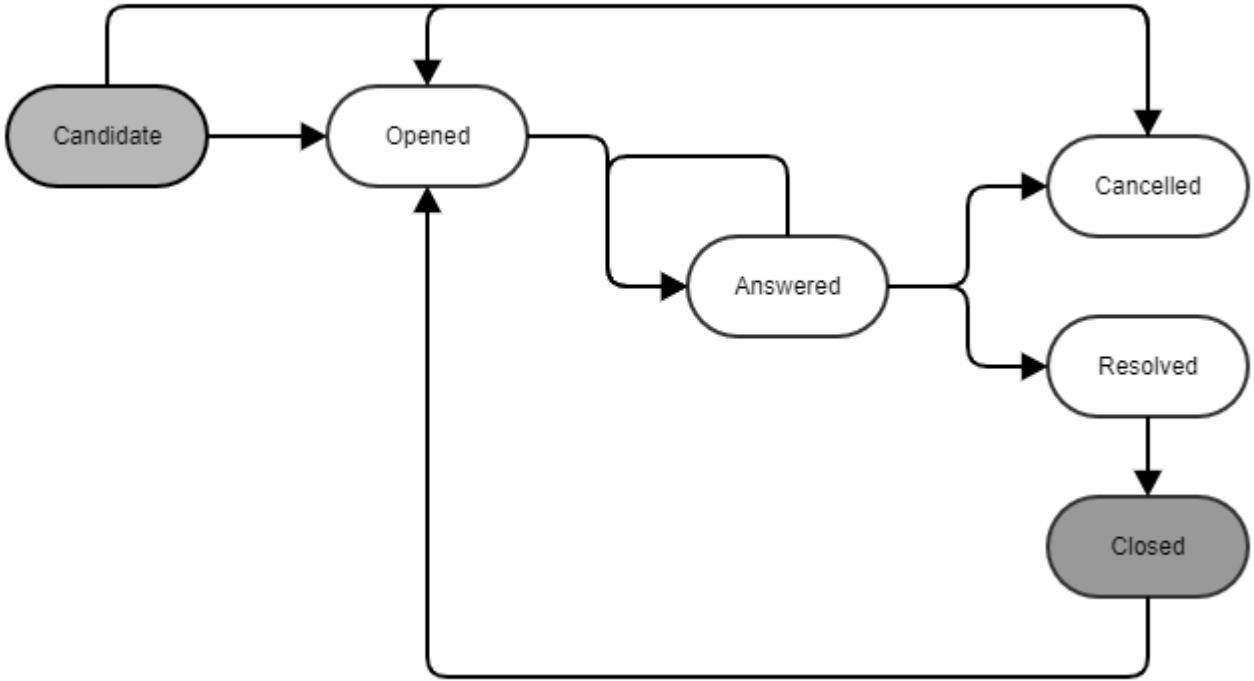
Relationship to Units Field

UnitsItemOID attribute on the ItemRef element

UnitsItemOID	oidref	*Optional*	Reference to the ItemDef that defines Units for variable defined by the referenced ItemDef.	The UnitsItemOID value must match the OID attribute for an ItemDef that defines the units for this Item.

https://wiki.cdisc.org/display/ODM2/ItemRef

Data Query Support



https://wiki.cdisc.org/display/ODM2/Query

Operational Datasets

SDTM-IG 3.1.2

- Annotated Case Report Forr
- Reviewers Guide
- Complex Algorithms
- ▸ Tabulation Datasets
- ▸ Value Level Metadata
- ▸ Controlled Terminology
- ▸ Computational Algorithms
- ▸ Comments

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xml	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xml	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xml	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xml	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xml	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xml	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide
SE	Subject Elements	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, TAETORD, ETCD	se.xml	
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, SVSTDTC, VISITNUM	sv.xml	
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMSTDTC, CMENDTC, CMCAT, CMTRT, CMDOSTXT, CMDOSU, CMINDC, CMDOSFRQ	cm.xml	
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXSTDTC, EXENDTC, EXTRT	ex.xml	

Other Updates

Additional Enhancements:

- Relationship to Units
- Expanded multi-language support
- Null Flavors
- Updated AdminData
- Dataset-JSON
- REST API Specification*
- ODMPath*
- Enhanced schema validation*

Deprecated:

- FormDef
- Presentation
- ItemData[Type]
- Certificate
- BasicDefinitions
- Annotations
- AuditRecords

* Released as ODM v2.0 supplements

Thank You!

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