

# Define-XML v2.0

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## Define-XML v2.0

- ✓ Draft version available since September 2012
- ✓ Final version expected in March 2013 (?)
- ✓ Define-XML v1.0 => Define-XML v2.0
  - “Major overhaul“, higher complexity
  - Change to ODM Version 1.3.1
- ✓ Draft Define-XML v2.0 => Final Define-XML v2.0
  - Minor changes only
- ✓ Define-XML v2.0 applicable for SDTM, ADaM, SEND

## Define-XML v2.0 Package includes ...

### ✓ Specifications

- General specifications with illustrations for the broad public
- Technical specifications for implementers/tool developers

### ✓ Summary of new features

### ✓ Sample SDTM define.xml

### ✓ Sample ADaM define.xml

### ✓ Updated Stylesheet applicable for SDTM+ADaM

- stable back button, no supportive files needed (e.g. .css, .gif)

# Define-XML v2.0 - Technical Specifications

## ✓ Specifications consist of

- Rules that can be tested by XML schema validation
- Business rules
  - e.g., for CDISC CTs use CDISC CT long name as Codelist Name
  - e.g., for each variable with Origin=Derived provide a MethodDef

## ✓ Conversion stylesheet will be provided to facilitate the migration

- It can create a file which passes XML schema validation
- It will probably not satisfy all business rules
  - Prospective creation of a define.xml v2.0 via new tools recommended

# Controlled Terminology: Enumerated Items vs. Code Lists

Vital Signs Test Name, NCI Code: C67153 Reference Name (CL.VSTEST)
Code Value
Body Frame Size (C49680)
Diastolic Blood Pressure (C25299)
Height (C25347)
Pulse Rate (C49676)
Systolic Blood Pressure (C25298)
Weight (C25208)

Vital Signs Test Code, Reference Name (CL.VSTESTCD)	
Code Value	Code Text
DIABP (C25299)	Diastolic Blood Pressure
FRMSIZE (C49680)	Body Frame Size
HEIGHT (C25347)	Height
PULSE (C49676)	Pulse Rate
SYSBP (C25298)	Systolic Blood Pressure
WEIGHT (C25208)	Weight

## referred from

VSTESTCD	Vital Signs Test Short Name	text	<a href="#">CL.VSTESTCD</a>	Assigned		
VSTEST	Vital Signs Test Name	text	<a href="#">CL.VSTEST</a>	Page <a href="#">11</a>		

# Value Level Metadata

LBTESTCD	Lab Test or Examination Short Name	text	<a href="#">CL.LBTESTCD</a>	Assigned		
LBTEST	Lab Test or Examination Name	text	<a href="#">CL.LBTEST</a>	eDT		
LBCAT	Category for Lab Test	text		eDT		
<a href="#">LBORRES</a>	Result or Finding in Original Units	text		eDT		



Value Level Metadata (VL.LB.LBORRES)					
Variable	Where	Type	Controlled Terms or Format	Origin	Computation Method
LBORRES	<a href="#">LBTESTCD</a> EQ BILI AND <a href="#">LBCAT</a> EQ CHEMISTRY AND <a href="#">LBSPEC</a> EQ BLOOD	float		eDT	
LBORRES	<a href="#">LBTESTCD</a> EQ BUN AND <a href="#">LBCAT</a> EQ CHEMISTRY AND <a href="#">LBSPEC</a> EQ BLOOD	float		eDT	
LBORRES	<a href="#">LBTESTCD</a> EQ GLUC AND <a href="#">LBCAT</a> EQ CHEMISTRY AND <a href="#">LBSPEC</a> EQ BLOOD	float		eDT	
LBORRES	<a href="#">LBTESTCD</a> EQ GLUC AND <a href="#">LBCAT</a> EQ URINALYSIS AND <a href="#">LBSPEC</a> EQ URINE AND <a href="#">LBMETHOD</a> EQ DIPSTICK	text	<a href="#">CL.UGLUC</a>	eDT	
LBORRES	<a href="#">LBTESTCD</a> EQ GLUC AND <a href="#">LBCAT</a> EQ URINALYSIS AND <a href="#">LBSPEC</a> EQ URINE AND <a href="#">LBMETHOD</a> EQ QUANT	float		eDT	

# Links to External Documents

EGDRVFL	Derived Flag	text	<a href="#">CL.NY</a>	Derived	Equal to Y for derived EGTESTCDs QTCB and QTCF  Complex Algorithms ( <a href="#">complexalgorithms.pdf</a> )
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```
<ItemRef ItemOID="IT.EG.EGDRVFL" OrderNumber="15" Mandatory="No" MethodOID="MT.EGDRVFL" />
```

```
<ItemDef OID="IT.EG.EGDRVFL" Name="EGDRVFL" DataType="text" Length="1" SASFieldName="EGDRVFL">
  <Description>
    <TranslatedText xml:lang="en">Derived Flag</TranslatedText>
  </Description>
  <CodeListRef CodeListOID="CL.NY" />
  <def:Origin Type="Derived" />
</ItemDef>
```

```
<MethodDef Type="Computation" OID="MT.EGDRVFL" Name="Algorithm to derive EGDRVFL">
  <Description>
    <TranslatedText xml:lang="en">Equal to Y for derived EGTESTCDs QTCB and QTCF</TranslatedText>
  </Description>
  <def:DocumentRef leafID="LF.ComplexAlgorithms">
    <def:PDFPageRef PageRefs="EG" Type="NamedDestination" />
  </def:DocumentRef>
</MethodDef>
```

```
<def:leaf ID="LF.ComplexAlgorithms" xlink:href="complexalgorithms.pdf">
  <def:title>Complex Algorithms</def:title>
</def:leaf>
```

## References

- ✓ Draft Define-XML v2.0  
(<http://www.cdisc.org/define-xml>)
- ✓ CDISC Standards Update Webinar of July 2012  
(<http://www.cdisc.org/presentations---slides>)