



My New XML Friend

Show and Tell

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Opinions herein are my own and are not intended to reflect the position of Accenture as an organization

What is a DefineXML?

Helps the FDA understand
the data in a clinical trial

Standards Applied

Derived vs
Collected
Variables

Data Sources

Initial XML Literacy

0

Also known as none, nichts, nada,
none to speak of

Warning Message

xpath

```
//ItemDef[@OID='CE.CEOUT']/def.ValueListRef[@ValueListOID='OUT']
```

| Variables | Values | Message |
|---------------|--------|-----------------------------------------|
| @ValueListOID | OUT | Referenced 'def.ValueListDef' not found |

Can I Find These in the XML code?

xpath

```
/ItemGroupDef[@OID='IG.DM']/ItemRef[@ItemOID='IT.DM.ACTARM']
```

Message

```
Required attribute 'Mandatory' is empty
```

Why are the Examples in the Front?

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I Found the Rules! —in the back

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A User Friendly Name

Name ▲



DefineXML.onepkg

Connections

Organizing the Define

- ▶ Tabulation Datasets
- ▶ Value Level Metadata
- ▶ Controlled Terminology
- ▶ Computational Algorithms



```
< Value Level Metadata (def:ValueListDef) >  
< Where Clause Definitions (def:WhereClauseDef) >  
< Domain Level Metadata (ItemGroupDef) >  
< Variable Level Metadata (ItemDef) >  
< Controlled Terminology Metadata (CodeList) >  
< Computational Algorithms (MethodDef) >
```

From Browser to Code

Computational Algorithms

| Method | Type | Description |
|--------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --DY | Computation | --DY = (date portion of --DTC) - (date portion of RFSTDTC) + 1 (if --DTC is on or after RFSTDTC) or --DY = (date portion of --DTC) - (date portion of RFSTDTC) (if --DTC precedes RFSTDTC) |

```
<MethodDef Name="--DY" OID="MT.--DY" Type="Computation">  
  <Description>  
    <TranslatedText xml:lang="en">--DY = (date portion of --DTC) - (date portion of RFSTDTC) + 1  
    (if --DTC is on or after RFSTDTC) or --DY = (date portion of --DTC) - (date portion of RFSTDTC)  
    (if --DTC precedes RFSTDTC)</TranslatedText>  
  </Description>  
</MethodDef>
```

Comments and Questions

P!N!M!

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