Setting the
Global Standard
for Clinical Data

Overview of CDISC standards and use cases along the E2E data management process

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REMINDER
why we are doing this

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Study #2 – dmg.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #3 – axd222.xpt

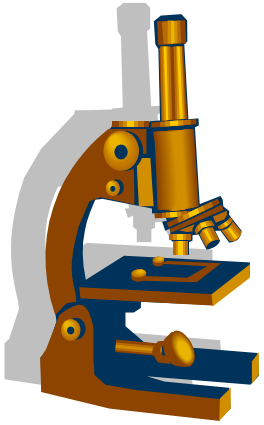
USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Study #4 – dmgph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

janus
Data to Knowledge

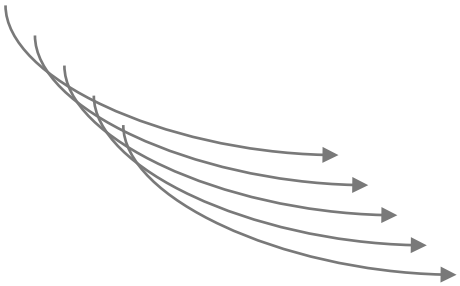
The speaker's view on CDISC

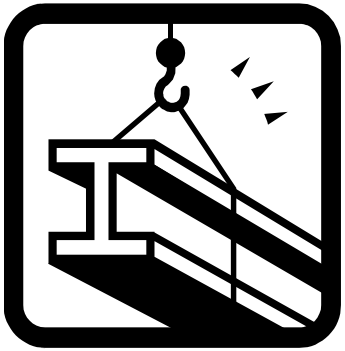


Sh. Semantics

~~**Terminology**~~

How do we call things?





Structure

Where do we put things?

- Protocol (PRG)
- CRF pages (**ODM,** CDASH)
- Lab forms (LAB)
- Data tables (SDTM, **define.xml**)
- Analysis tables (ADaM)

Format

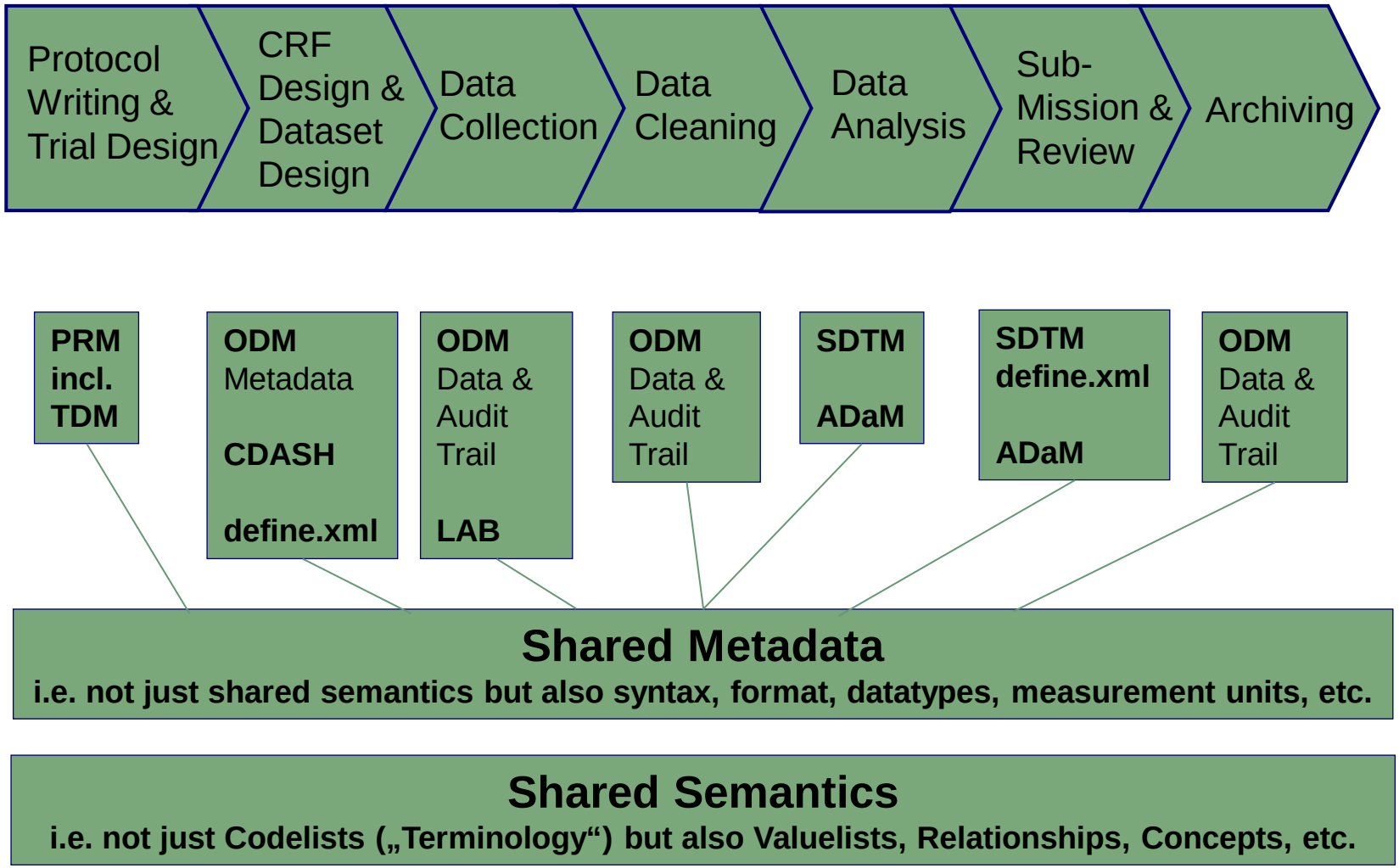
How do computers store and exchange things?

- XML (**ODM**)
- ~~ASCII~~
- ~~SAS~~

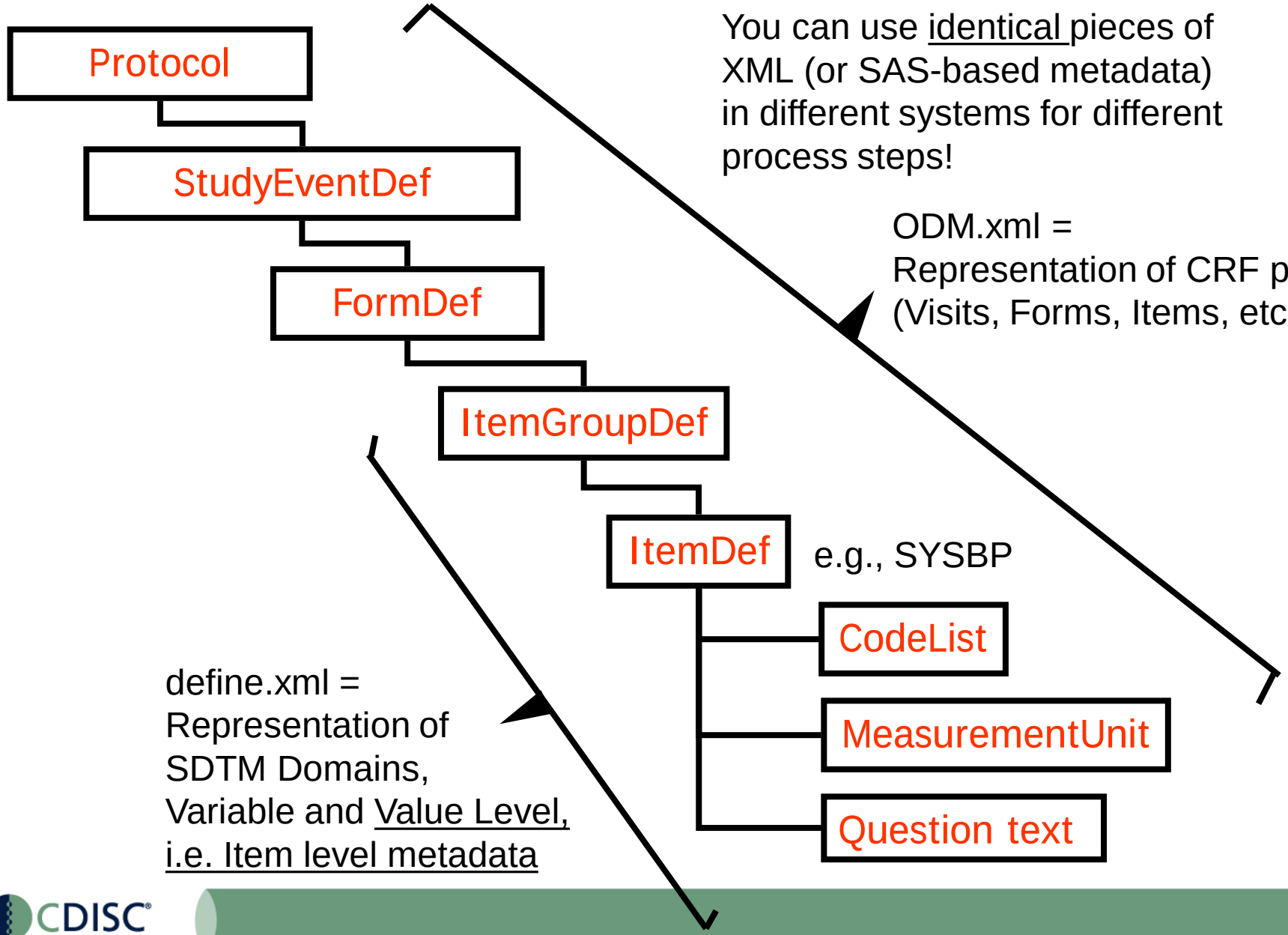
CDISC Production Standards – Where are we now?

Standard	Description	Implementation Release Date
Terminology & Shared Semantics	Developing standard terminology and shared semantics to support all CDISC standards	**2006 and ongoing**
Protocol Representation (incl. Trial Design)	Collaborative effort to develop machine-readable standard protocol with data layer	**V 1.0 draft for comment till June 2009**
ODM	Standard for CRF metadata, data acquisition, exchange, submission (define.xml) and archive	**2001***
CDASH	Clinical Data Acquisition Standards Harmonization (content standard on top of ODM)	**2008**
LAB	Standard available for transfer of clinical lab data	**2002**
SDTM, SEND	Ready for regulatory submission of CRT V3.1.2 SDTM Implementation Guide	**2004*** **Mar 2009**
Define.xml	Standard for SDTM metadata (Case Report Tabulation Data Definition Specification)	**2005***
ADaM	General Considerations document and examples of datasets for submission. New Implementation Guide due 3-4Q2009	**2004** **New IG 2009**

E2E data management use cases



Metadata sharing, e.g. between ODM and define.xml



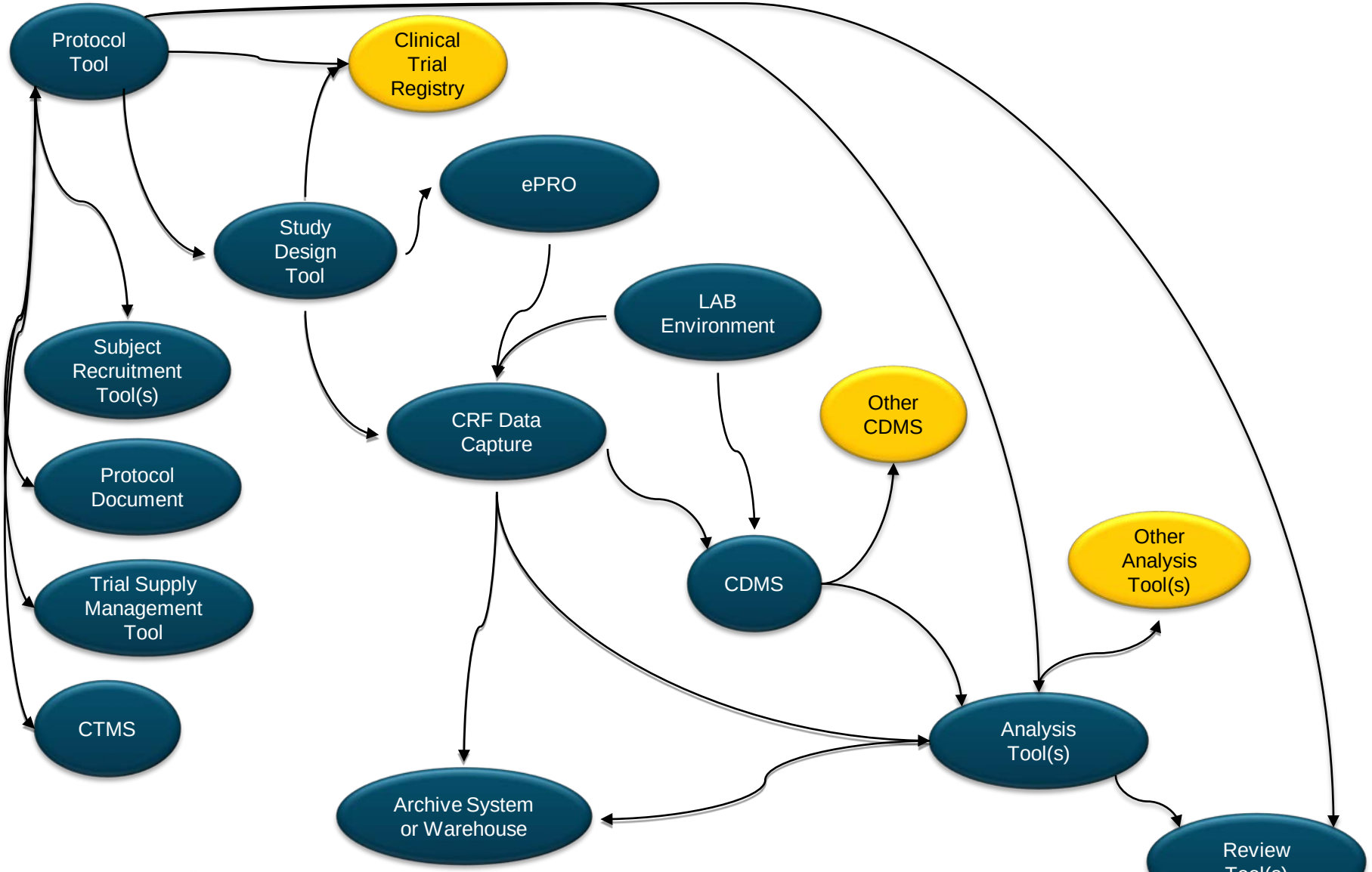
But the devil is in the detail …

```
<ItemDef OID="VS.SYSBP"
    Name="Systolic Blood Pressure“      /      Name=“SYSBP”
    def:Label=“Systolic Blood Pressure"
    DataType=“integer"
    Length=“3"
    SASFieldName="SYSBP“   SDSVarName="SYSBP">
     <Question>
          <TranslatedText xml:lang="en">Systolic Blood Pressure</TranslatedText>
          <TranslatedText xml:lang="de">Systolischer Blutdruck</TranslatedText>
     </Question>
     <MeasurementUnitRef MeasurementUnitOID=“MU.mmHg"/>
</ItemDef>
```

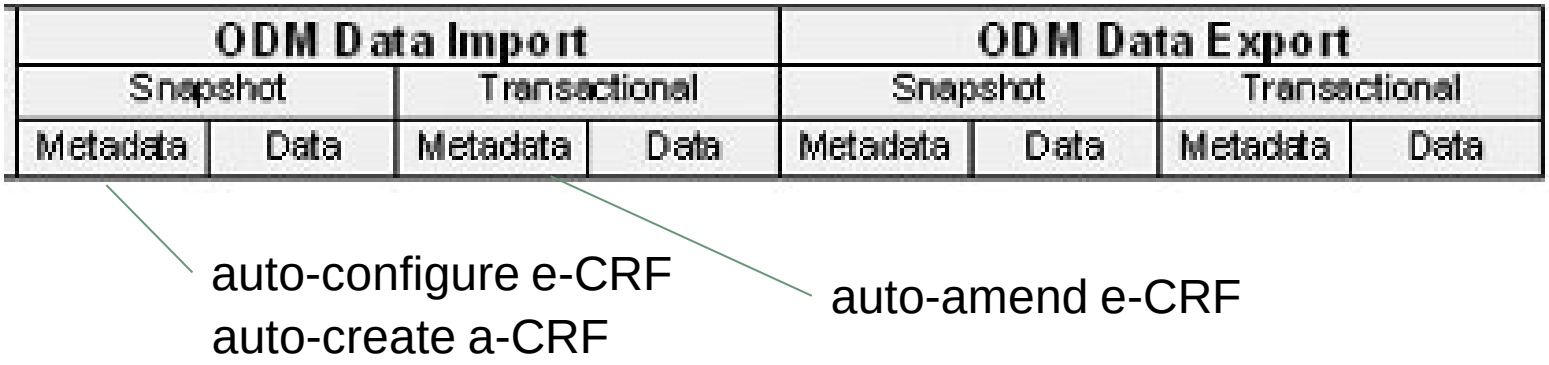
define.xml

ODM.xml

Use cases for data transfer: system view



Use cases for data transfer: ODM view



- Software tools are certified for each of these separate use cases.

- These standard use cases allow for painless exchange between systems of different vendors!

The E2E process can have many variations

- Example 1: how to create CRF metadata (ODM)
  - copy from a metadata repository
  - import from another tool (e.g. a PRM/TDM tool)
  - create from scratch with a design tool

- Example 2: how to move data from EDC/CDM database into SDTM datasets in SAS
  - proprietary SDTM export mechanism in the EDC system
  - certified export to ODM, load ODM into SAS, transform to SDTM with SAS tools
  - certified export to ODM, transform to SDTM with XML technology, load SDTM into SAS (PROC SQL)