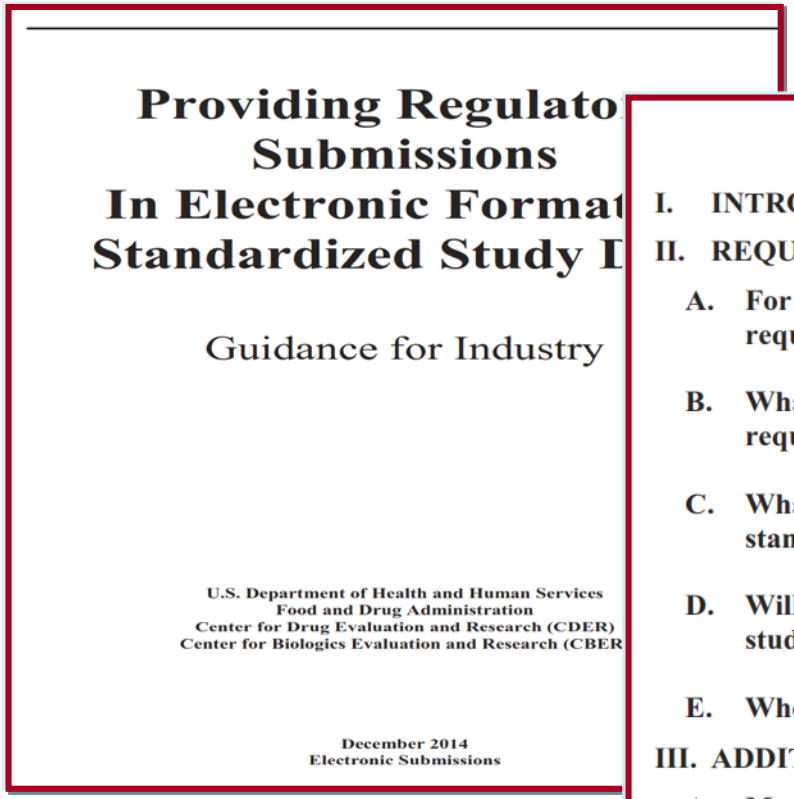
Data Sharing Standards

Guidance for data submission standards



Providing Regulato
Submissions
In Electronic Format
Standardized Study D

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER

December 2014
Electronic Submissions

TABLE OF CONTENTS

Guidance for data submission standards

II. REQUIREMENT TO SUBMIT ELECTRONIC STANDARDIZED STUDY DATA

A. For what submission types is an electronic submission of standardized study data required?

Electronic submissions of standardized study data will be required for the following submission types:

- Certain investigational new drug applications (INDs)[4,5]
- New drug applications (NDAs)
- Abbreviated new drug applications (ANDAs)
- Certain biologics license applications (BLAs)[6]

Epidemiological studies are now adopted this standards

This requirement also includes all subsequent submissions, including amendments, supplements, and reports to one of the submission types identified above. Study data in submissions that are not submitted electronically will not be filed, unless exempt from the electronic submission requirements or unless FDA has granted a waiver.

Sponsors and applicants must submit study data electronically using the format described in this guidance for both clinical and nonclinical studies.

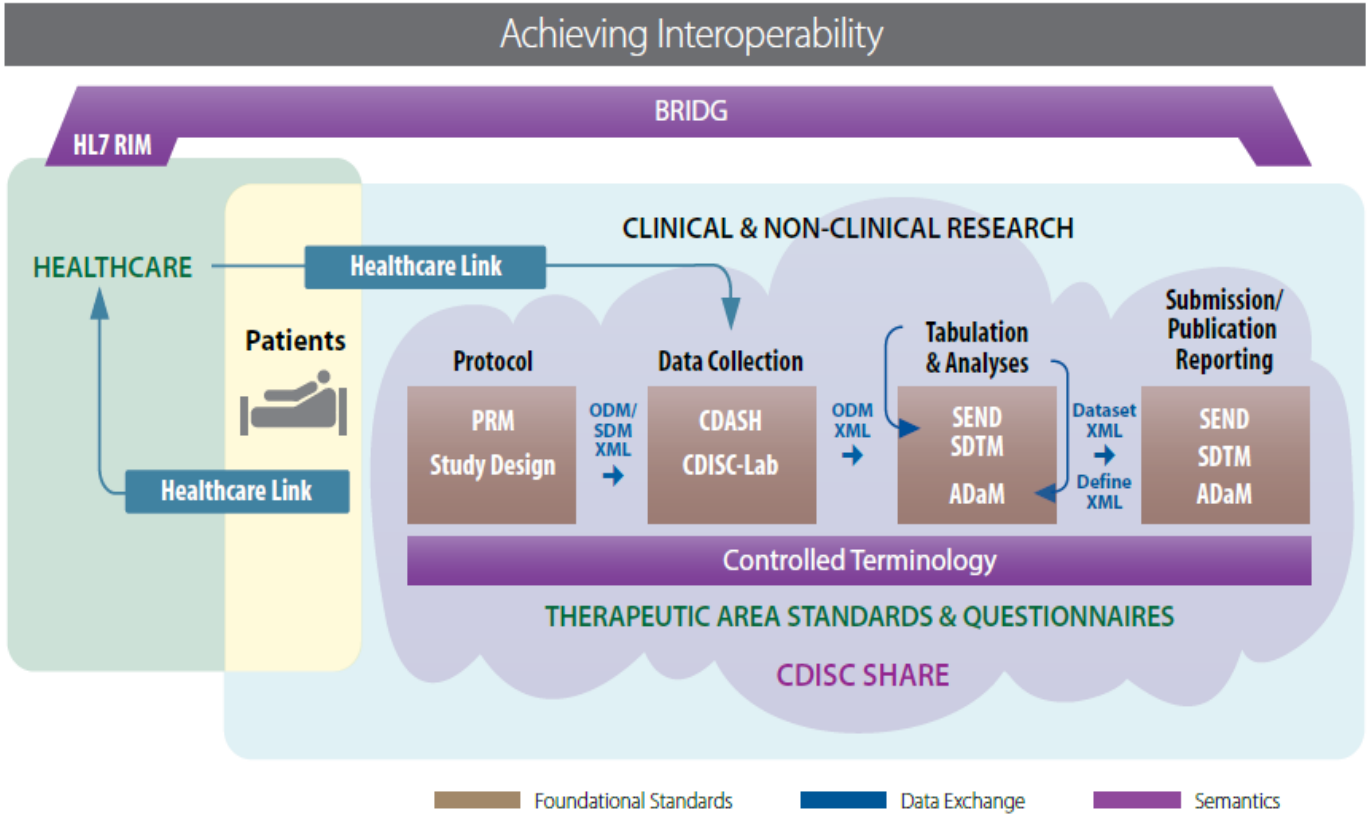
Guidance for data submission standards

3. Controlled Terminology Standard

The use of controlled terminology standards, also known as vocabularies, is an important component of study data standardization and is a critical component of achieving semantically interoperable data exchange.[11] Controlled terminology standards specify the key concepts that are represented as preferred terms, definitions, synonyms, codes, and code systems. Controlled terminology standards are maintained by external organizations (i.e., external to the sponsor or applicant). Sponsor- or applicant-defined custom terms are not considered controlled terminologies. However, some controlled terminologies are extensible and permit additions to existing codelists. It is the expectation that sponsors or applicants will use the controlled terminologies maintained by external organizations as the standard. Examples of controlled terminology standards include:

- The National Drug File (NDF) — Reference Terminology for drug classifications[12]
- CDISC Controlled Terminology[13]
- Medical Dictionary for Regulatory Activities (MedDRA)[14]

Clinical Data Interchange Standards Consortium (CDISC)



Source: file:///D:/My%20Documents/Downloads/Data_Standards_&_Clinical_Data_Interchange_Standards_Consortium_(CDISC).pdf

Data Standards for Sharing

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

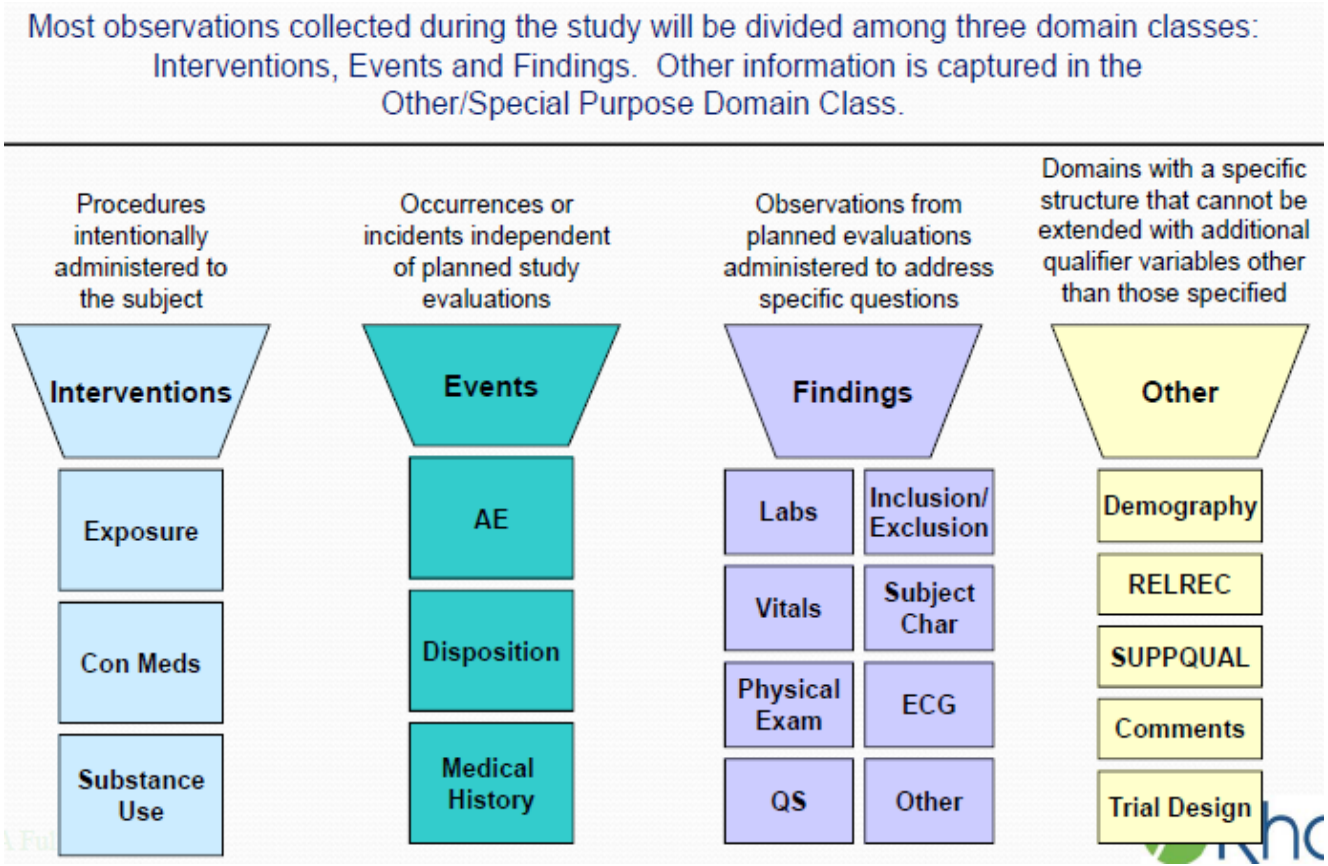
CDISC Models

- **Study Data Tabulation Model (SDTM)**
  - Version 3.1.1 and 3.1.2 accepted by FDA
  - Referenced as specification in FDA Guidance on eSubmissions for Implementation of ICH eCommon Technical Document
- **Analysis Dataset Models (ADaM)**
  - ADaM Version 2.1 and Implementation Guide Version 1.0 released 12/09
  - Accepted by FDA
- **Clinical Data Acquisition Standards Harmonization (CDASH)**
  - recommended basic standards for the collection of clinical trial data
  - Version 1.1 released January 2011
- **Operational Data Model (ODM)**
  - Production Version 1.3
  - XML schema
  - Part of eCTD data specifications
- **Protocol Representation Model**
  - Version 1.0 released May 2009
  - Spreadsheet of protocol elements with definitions; documentation; initial HL7 model
- **Laboratory Data Model (LAB)**
  - Production Version 1.0.1
  - Implementations through SAS, ASCII, XML/ODM and HL7 V3 RIM message
- **Standards for the Exchange of Non-clinical Data (SEND)**
  - Version 2.3 released November 2005. Based upon CDISC SDS V3.1
  - Included in SDTM model now referenced in FDA Guidance

Rho
Giving flight to research

Source: Carol Baker, Jeff Abolafia, Rob Woolson Data Standards & CDISC. Rhoworld.com

Data Sharing Models



Source: Carol Baker, Jeff Abolafia, Rob Woolson Data Standards & CDISC. Rhoworld.com

Data Standard Modules for Sharing

Special-Purpose Domains (defined in Section 5):

- Demographics — DM
- Comments — CO
- Subject Elements — SE
- Subject Visits — SV

Interventions General Observation Class (defined in Section 6.1):

- Concomitant Medications — CM
- Exposure — EX
- Substance Use — SU

Events General Observation Class (defined in Section 6.2):

- Adverse Events — AE
- Disposition — DS
- Medical History — MH
- Protocol Deviations — DV
- Clinical Events — CE

Findings General Observation Class (defined in Section 6.3):

- ECG Test Results — EG
- Inclusion/Exclusion Criterion Not Met — IE
- Laboratory Test Results — LB
- Physical Examination — PE
- Questionnaires — QS
- Subject Characteristics — SC
- Vital Signs — VS
- Drug Accountability — DA
- Microbiology Specimen — MB
- Microbiology Susceptibility Test — MS
- PK Concentrations — PC
- PK Parameters —PP

Findings About (defined in Section 6.4)

- Findings About — FA

Trial Design Domains (defined in Section 7):

Source: Carol Baker, Jeff Abolafia, Rob Woolson Data Standards & CDISC. Rhoworld.com

Data Standard Modules for Sharing

2.2.1 The Interventions Observations Class

Table 2.2.1: Interventions — Topic and Qualifier Variables, One Recor … Intervention Episode

Variable Name	Variable Label	Type	Role	
			Topic Variable	
--TRT	Name of T…			
--MODIFY	Modified Treatment			
--DECOD	Standardiz… Treatment			
--MOOD	Mood			
--CAT	Category			
--SCAT	Subcatego…			

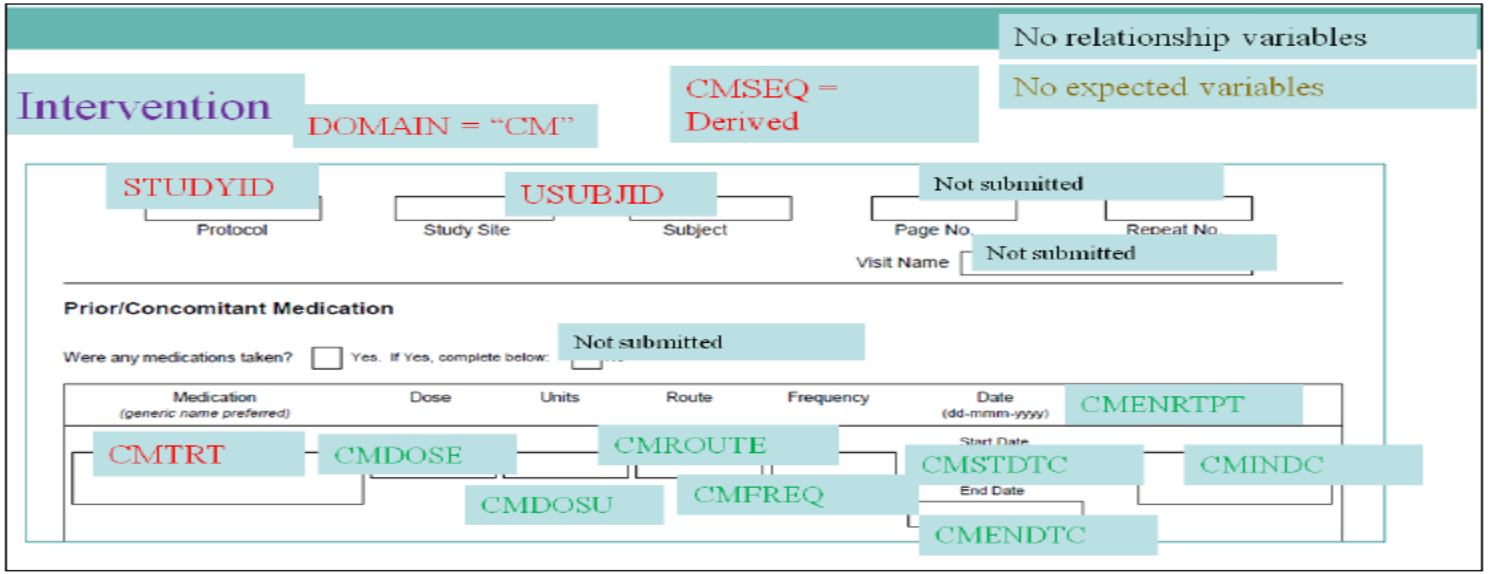
Data Class
Required
Expected
Permissible
Relationship

CDISC

Study Data Tabulation Model
Version 1.4

Prepared by the
CDISC Submission Data Standards Team

FIGURE 7 – INTERVENTIONS EXAMPLE



Source: http://www.lexjansen.com/phuse/2012/is/IS04.pdf

Data Standard Modules for Sharing

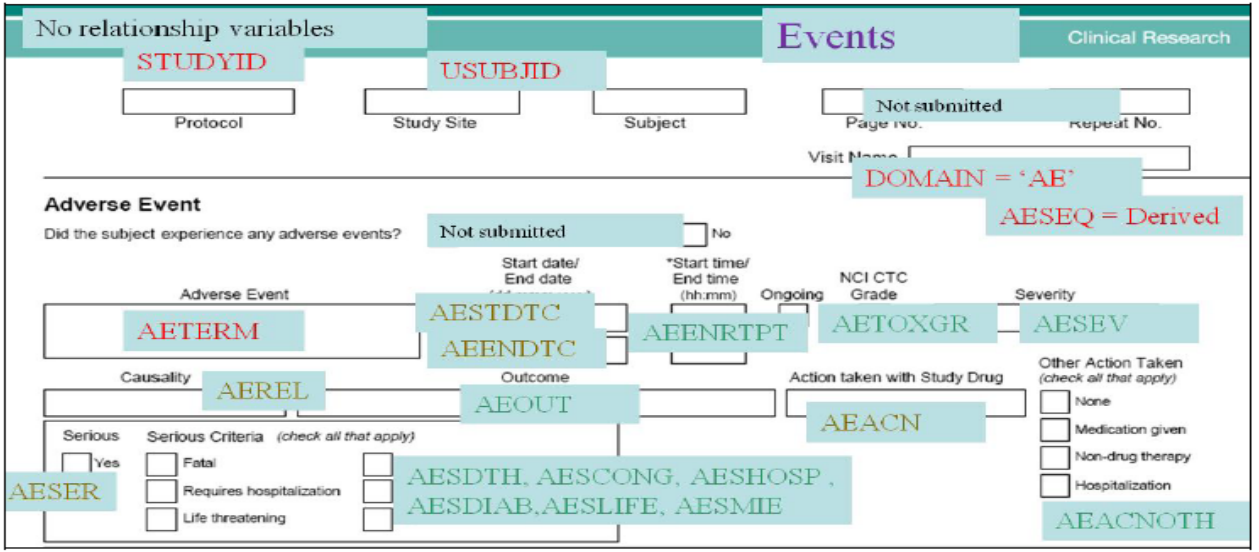
2.2.2 The Events Observation Class

Table 2.2.2: Events — Topic and Qualifier Variables, One Record per Event

Variable Name	Variable Label	Type	Role	Description
Topic Variable				
--TERM	Reported Term	Char	Topic	Topic variable for an event observation, which is the verba
--MODIFY	Modified Reported Term	Char		
--LLT	Lowest Level Term	Char		
--LLTCD	Lowest Level Term Code	Num		
--DECOD	Dictionary-Derived Term	Char		

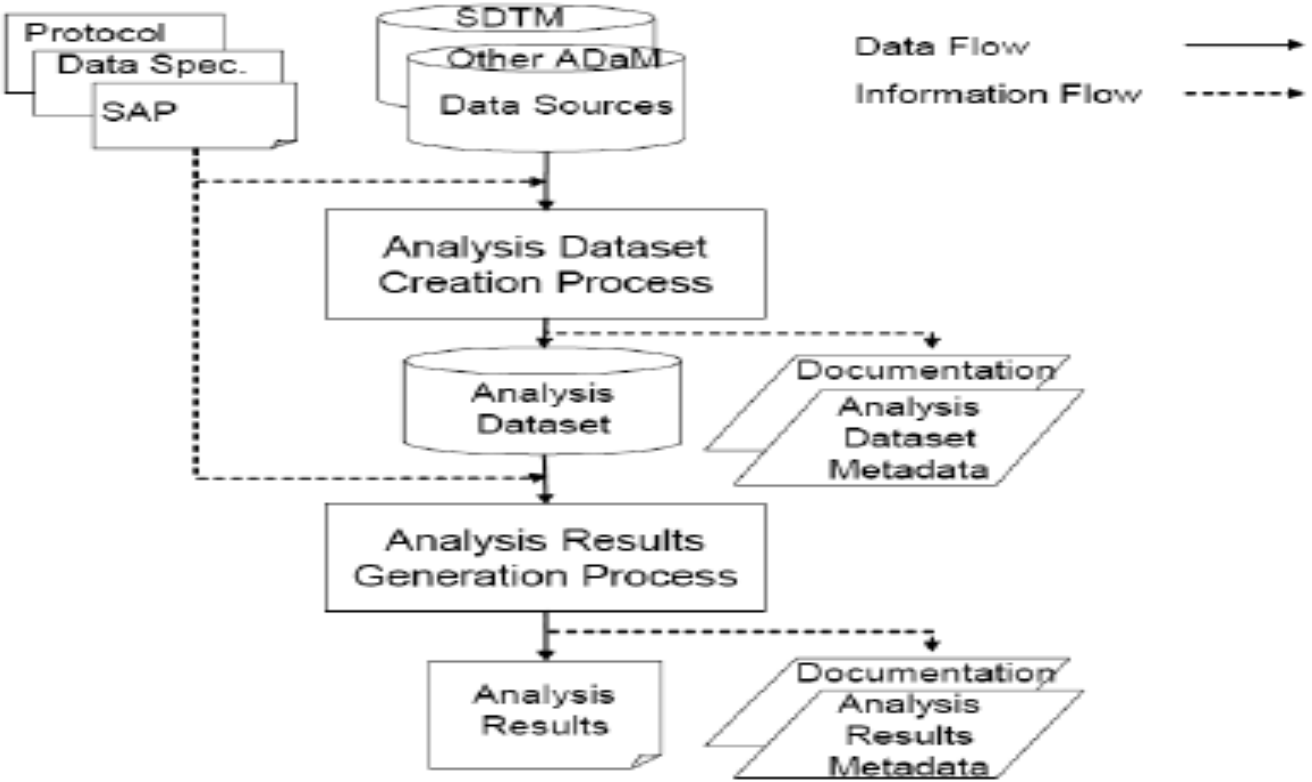
Data Class
Required
Expected
Permissible
Relationship

FIGURE 8 – EVENTS EXAMPLE



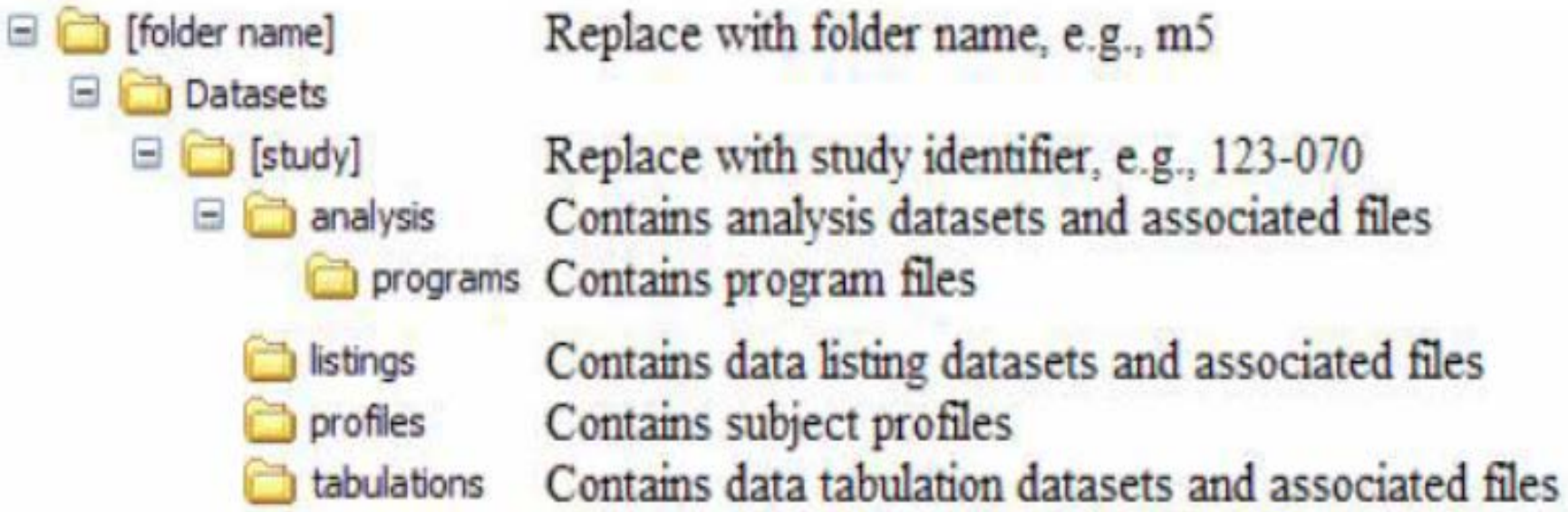
Source: http://www.lexjansen.com/phuse/2012/is/IS04.pdf

Data Standards for Traceability



Source: Carol Baker, Jeff Abolafia, Rob Woolson Data Standards & CDISC. Rhoworld.com

Data Standards for Submision



Source: Carol Baker, Jeff Abolafia, Rob Woolson Data Standards & CDISC. Rhoworld.com