CDISC Open-Source Alliance (COSA) Spotlight
Define-XML Style Sheets

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Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- The author has no real or apparent conflicts of interest to report.

About Lex Jansen

- 16 years in an IT/Standards role in Biostatistics at Organon
- 4 years as a consultant to help companies implement CDISC
- 10 years at SAS
  - 7 years as Principal Software Developer working on SAS Clinical Standards Toolkit (implementing mostly XML based standards (Define-XML, ODM, Dataset-XML)) and SAS Life Science Analytics Framework (Java).
  - 3 years as Principal Solution Consultant implementing SAS Life Science Analytics Framework
- Since November 2021: Senior Director, Data Science Development at CDISC (contract through Lex Jansen Consulting LLC)

- Core member of the CDISC Data Exchange Standards team since 2008. Co-lead since November 2021
- Core member of the CDISC Define-XML development team.
  - One of the main **Define-XML v2** developers.
  - Developer of CDISC/PhUSE **Define-XML v2.x XSL stylesheets**.
- Core member of the CDISC **Dataset-XML** development team.
- Core member of ADaM Metadata team
  - One of the main developers of the **Analysis Results Metadata** v1.0 for Define-XML v2.0 extension

Agenda

1. What is Define-XML
2. Displaying Define-XML using Style Sheets
3. The project

What is Define-XML?

- An XML based machine-readable metadata exchange standard used to describe any tabular dataset structure
- Primary use case: describe CDISC Study Data Tabulation Model (SDTM), Standard for Exchange of Nonclinical Data (SEND), and Analysis Data Model (ADaM) datasets for the purpose of submissions to regulatory authorities
- Required by FDA (USA) and PMDA (Japan) and preferred by NMPA (China) for all CDISC submissions

What is Define-XML?

Separate data definition files should be included for each type of electronic dataset submission, i.e., a separate data definition file for the SDTM datasets of a given clinical study, a separate data definition file for the SEND datasets of a given nonclinical study, and a separate data definition file for the ADaM datasets of a given clinical study. The data definition file should be submitted in XML format, i.e., a properly functioning define.xml[42]. In addition to the define.xml, a printable define.pdf should be provided if the define.xml cannot be printed.[43] To confirm that a define.xml is printable within the CDER IT environment, it is recommended that the sponsor submit a test version to cder-edata@fda.hhs.gov prior to application submission. The Catalog lists the currently supported version(s) of define.xml. It should be noted that define.xml version 2.0 is the preferred version. Sponsors should include a reference to the style sheet as defined in the specification (as listed in the Catalog) and place the corresponding style sheet in the same submission folder as the define.xml file. Within the eCTD study tagging file (STF), valid file-tags for define.xml are 'data-tabulation-data-definition' for SEND or SDTM datasets or 'analysis-data-definition' for ADaM datasets.

Study Data Technical Conformance Guide v4.9 (March 2022)
(https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources)

Displaying Define-XML – RAW


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Displaying Define-XML – RAW – formatted

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  <ItemRef ItemOID="IT.DIPARM" Mandatory="Yes" OrderNumber="6"/>
  <ItemRef ItemOID="IT.DIVAL" Mandatory="Yes" OrderNumber="7"/>
  <def:Class Name="SPECIAL PURPOSE"/>
  <def:leaf ID="LF.DI" xlink:href="di.xpt">
    <def:title>di.xpt</def:title>
  </def:leaf>
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  </Description>
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  <ItemRef ItemOID="IT.DM.DOMAIN" Mandatory="Yes" OrderNumber="2"/>
  <ItemRef ItemOID="IT.USUBJID" Mandatory="Yes" OrderNumber="3" KeySequence="2" MethodOID="MT.USUBJID"/>
```

Displaying Define-XML

CDISC01

- Annotated Case Report Form
- ▸ Supplemental Documents
- ▸ Datasets
- ▾ Controlled Terminology
  - ▸ CodeLists
  - ▸ External Dictionaries
- ▸ Methods

Expand all VLM

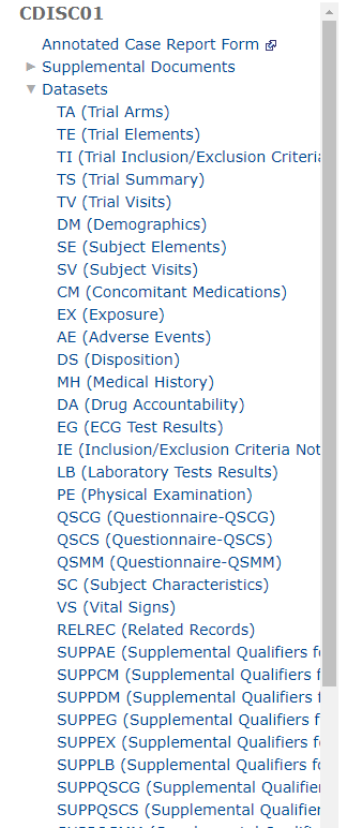
Collapse all VLM

Study Name	CDISC01
Study Description	CDISC Test Study
Protocol Name	CDISC01
Metadata Name	Study CDISC01, Data Definitions
Metadata Description	Study CDISC01, Data Definitions

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD		ta.xpt
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD		te.xpt
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD		ti.xpt
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ		ts.xpt
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD		tv.xpt
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide [section2.1]	dm.xpt
SE	Subject Elements	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, TAETORD, ETCD		se.xpt
SV	Subject Visits	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, SVSTDTC, VISITNUM		sv.xpt
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or	Tabulation	STUDYID, USUBJID, CMSTDTC, CMENDTC,		cm.xpt

Displaying Define-XML



VS (Vital Signs) - FINDINGS

Location: vs.xpt

Related Supplemental Qualifiers Dataset: SUPPVS (Supplemental Qualifiers for VS)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (VS) • "VS" = "Vital Signs"	Assigned
USUBJID		Unique Subject Identifier	text	14		Derived Concatenation of STUDYID and SUBJID Formal Expression
VSSEQ		Sequence Number	integer	2		Derived Sequential number identifying records within each USUBJID in the domain.
VSTESTCD		Vital Signs Test Short Name	text	20	Vital Signs Test Code [6 Terms]	Assigned
VSTEST		Vital Signs Test Name	text	24	Vital Signs Test Name [6 Terms]	CRF Annotated Case Report Form [11]
VSPOS		Vital Signs Position of Subject	text	7		CRF Annotated Case Report Form [11]
VSORRES VLM		Result or Finding in Original Units	text	30		CRF Annotated Case Report Form [11]
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure (Orig U)	integer	2		CRF Annotated Case Report Form [11]
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size (Orig U)	text	6	Size • "LARGE" • "MEDIUM" • "SMALL"	CRF Annotated Case Report Form [11]

Displaying Define-XML

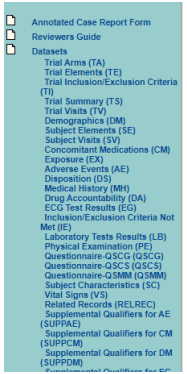
Neither the Define-XML specification, nor any regulatory Agency defines how a Define-XML document should be displayed.

A stylesheet is not part of the Define-XML standard.

However, **reviewers like predictability**!

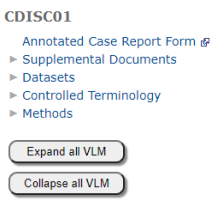
Datasets for Study 1234

Dataset	Description	Structure	Purpose	Keys	Location
DM	Demographics	Special Purpose - One record per event per subject	Tabulation	STUDYID, USUBJID	crt/datasets/1234/dm.xpt
TE	Trial Elements	Trial Design - One Record Per Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/te.xpt
TA	Trial Arms	Trial Design - One Record per Element for each Arm	Tabulation	STUDYID, ARM	crt/datasets/1234/ta.xpt
TV	Trial Visits	Trial Design - One Record per Visit per Arm	Tabulation	STUDYID, VISIT	crt/datasets/1234/tv.xpt
SE	Subject Elements	Study Design - One Record Per Subject Element	Tabulation	STUDYID, ELEMENT	crt/datasets/1234/se.xpt
SV	Subject Visits	Study Design - One Record Per Subject Visit	Tabulation	STUDYID, VISIT	crt/datasets/1234/sv.xpt
EX	Exposure	Interventions - One record per constant dosing interval per subject	Tabulation	USUBJID, EXTRT, EXSEQ	crt/datasets/1234/ex.xpt
CM	Concomitant Medications	Interventions - One record per event per subject	Tabulation	USUBJID, CMTRT, CMSEQ	crt/datasets/1234/cm.xpt
SU	Substance Use	Interventions - One record per substance use type per subject	Tabulation	USUBJID, SUTRT, SUSEQ	crt/datasets/1234/su.xpt
AE	Adverse Events	Events - One record per event per subject	Tabulation	USUBJID, AETERM, AESEQ	crt/datasets/1234/ae.xpt



Datasets for Study CDISC01

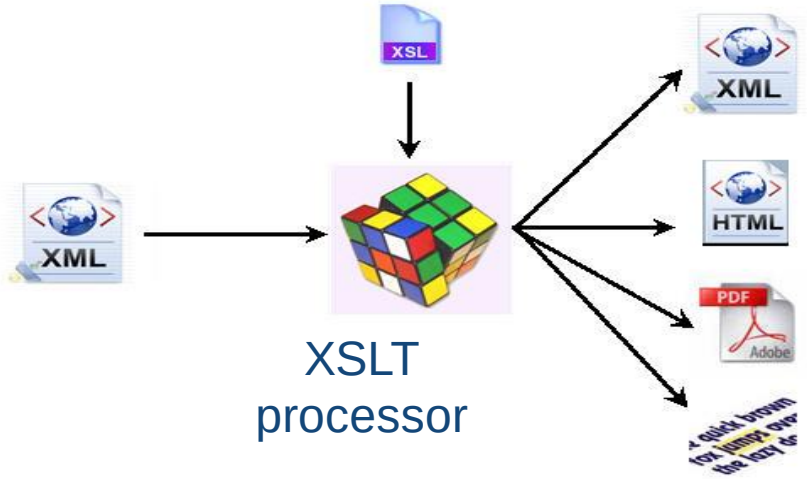
Dataset	Description	Class	Structure	Purpose	Keys	Location
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TI	Trial Inclusion/Exclusion Criteria	Trial Design	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt
TS	Trial Summary	Trial Design	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt
TV	Trial Visits	Trial Design	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt
DM	Demographics	Special Purpose	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
SE	Subject Elements	Special Purpose	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC, TAETORD, ETCD	se.xpt



Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD		ta.xpt
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD		te.xpt
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD		ti.xpt
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ		ts.xpt
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD		tv.xpt
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide [section2.1]	dm.xpt

Displaying Define-XML

- eXtensible Stylesheet Language Transformations (XSLT) is a language that lets you transform XML documents into other XML documents, into HTML documents, or into any other text-based document (CSV, JSON, code, …), or even a PDF file.
- XSLT is a language "for transforming the structure and content of an XML document"



Displaying Define-XML

- A **processor instruction** associates a stylesheet with an XML file

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="define2-0-0.xsl"?>
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
 xmlns:xlink="http://www.w3.org/1999/xlink"
 xmlns:def="http://www.cdisc.org/ns/def/v2.0"
 ODMVersion="1.3.2"
   ...
```

- A stylesheet processor can use the processor instruction to automatically apply the stylesheet ... (*but not in modern browsers on your local PC*)

Available Stylesheets

- CDISC provided sample stylesheets:
  - 2005 - Define-XML v1.0 (*"CRT-DDS"*)
  - 2011 - Metadata Submission Guideline (MSG) for SDTMIG (Define-XML v1.0)
  - 2014 - Define-XML v2.0
  - 2015 - Analysis Results Metadata (ARM) v1.0 for Define-XML v2.0
  - 2019 - Define-XML v2.1
- PHUSE working group published an updated and much stylesheet:
  - 2018 – Define-XML 2.0

Available Stylesheets

The latest Define-XML v2.0 and v2.1 stylesheets:

- Conform to web standards and follow accessibility guidelines
- Renders to HTML that is supported in modern browsers (Chrome, Firefox, MS Edge, Safari)
  - Internet Explorer is retiring soon
- Use JavaScript, but degrade gracefully when JavaScript is disabled
- Implement a special style for printing purposes (recommended: landscape)

- But where do you go with issues and bugs?
- Where do you find the latest stylesheets?

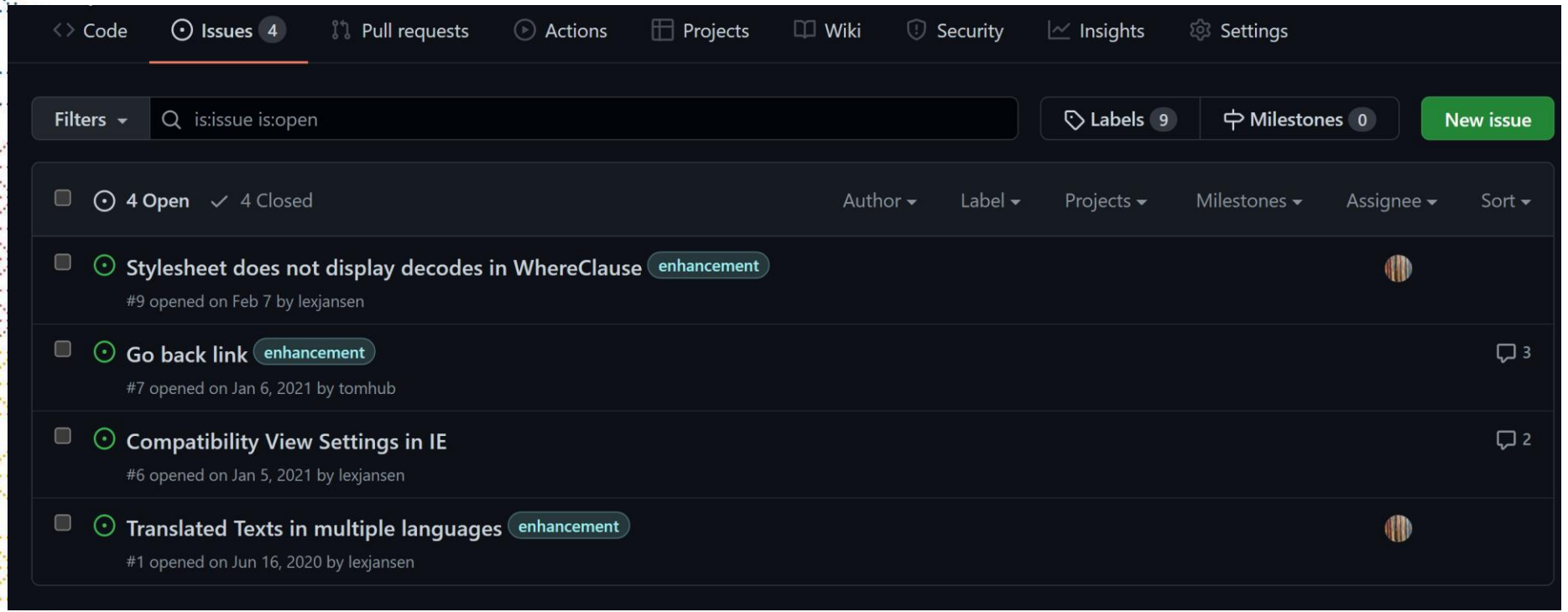
The COSA Project

Define-XML XSL Stylesheets

This projects provides a Define-XML v2.0 and v2.1 XSL stylesheet

- Provides a central location on GitHub for the latest Define-XML stylesheets
- Central location for submitting issues / feature requests
- Documentation of stylesheet usage
  (example: how to transform Define-XML to HTML outside of the browser)
- Scope is narrow: use case of electronic submissions to regulatory agencies
- Will not depend on the availability of an XSLT processor in the browser
  - Modern browsers do not allow transforming a local Define-XML document to HTML using an XSLT stylesheet reference for reasons of security
  - XSLT processors in the browser only support XSTL 1.0 (1999!)
  - Use an external XSLT processor to transform to HTML that can be opened in any browser

The Define-XML XSL Project: issue management



The Define-XML XSL Project: What's next

- Style sheet localization: **one** stylesheet for **many** languages
- The stylesheet uses a parameter (**interfaceLang**) to look up translations in a dictionary

```
<?xml version="1.0" encoding="utf-8"?>
<dictionary>
        <entry term="Class">
                <TranslatedText xml:lang="zh">类</TranslatedText>
                <TranslatedText xml:lang="ja">クラス</TranslatedText>
        </entry>
        <entry term="Code List">
                <TranslatedText xml:lang="zh">代码清单</TranslatedText>
                <TranslatedText xml:lang="ja">コードリスト</TranslatedText>
        </entry>
        <entry term="CodeLists">
                <TranslatedText xml:lang="zh">代码清单</TranslatedText>
                <TranslatedText xml:lang="ja">コードリスト</TranslatedText>
        </entry>
        <entry term="Collapse all VLM">
                <TranslatedText xml:lang="zh">收起所有VLM</TranslatedText>
                <TranslatedText xml:lang="ja">全てのVLMを折りたたむ</TranslatedText>
        </entry>
        <entry term="Comment">
                <TranslatedText xml:lang="zh">注释</TranslatedText>
                <TranslatedText xml:lang="ja">コメント</TranslatedText>
        </entry>
```

CDISC-Sample

- Supplemental Documents
- Datasets
- Controlled Terminology
- Methods

Expand all VLM

Collapse all VLM

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
ADSL	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	USUBJID	Screen Failures are excluded since they are not needed for this study analysis	adsl.xpt
ADQSADAS	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per	Analysis	USUBJID, PARAMCD, AVISIT, ADT	See referenced dataset creation program and Analysis Data Reviewer's	adqsadas.xpt

CDISC-Sample

- 補足文書
- データセット
- 統制用語
- メソッド

すべてのVLMを展開する

全てのVLMを折りたたむ

データセット

データセット	要約	クラス	構造	目的	キー	ドキュメンテーション	ロケーション
ADSL	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	USUBJID	Screen Failures are excluded since they are not needed for this study analysis	adsl.xpt
ADQSADAS	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per	Analysis	USUBJID, PARAMCD, AVISIT, ADT	See referenced dataset creation program and Analysis Data Reviewer's	adqsadas.xpt

CDISC-Sample

- 补充文件
- 数据集
- 受控术语
- 方法

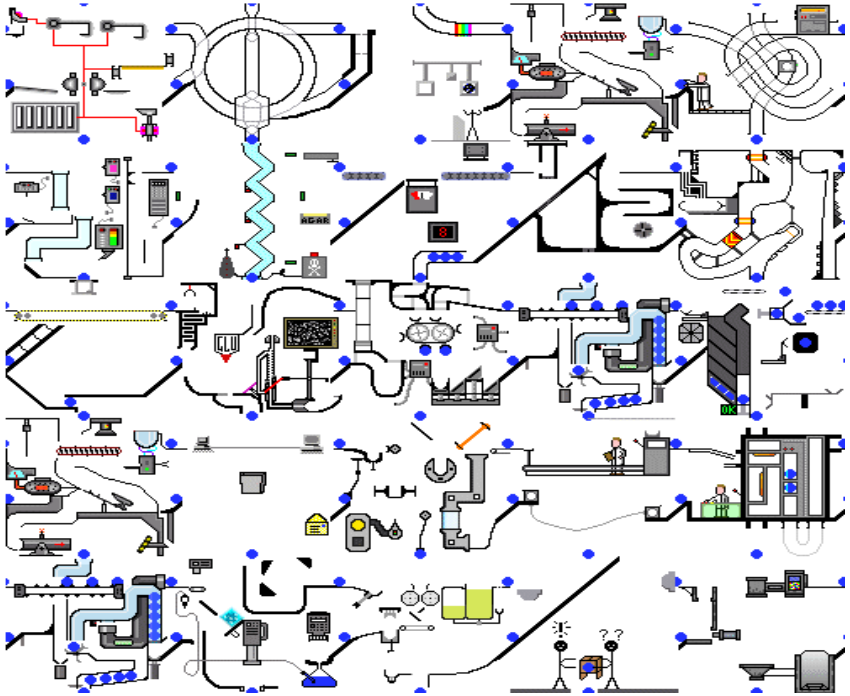
展开所有VLM

收起所有VLM

数据集

数据集	描述	类	结构	目的	按键	文献资料	位置
ADSL	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	USUBJID	Screen Failures are excluded since they are not needed for this study analysis	adsl.xpt
ADQSADAS	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per analysis visit per	Analysis	USUBJID, PARAMCD, AVISIT, ADT	See referenced dataset creation program and Analysis Data Reviewer's	adqsadas.xpt

Demo



- COSA Repository Directory: https://cosa.cdisc.org/
- Define-XML v2.0 GitHub Repository: https://github.com/lexjansen/define-xml-2.0-stylesheets
- Define-XML v2.1 GitHub Repository: https://github.com/lexjansen/define-xml-2.1-stylesheets
- Define-XML LinkedIn Group: https://www.linkedin.com/groups/4975366/

LinkedIn: https://www.linkedin.com/in/lexjansen/

Email: lexjansen@gmail.com
ljansen@cdisc.org

Web: https:\\www.lexjansen.com