

## **Excel-like Data Definition Editor for Real-time Generation of Define.xml and Mapping specs Management**

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### **ABSTRACT**

Define.xml is mandatory for study data submissions to regulatory agencies. CDISC Mapping specs management is crucial in the process of SDTM and ADaM datasets creation. Users are eager to have an Excel-like Data Definition Editor (DDE) that is specialized for Define.xml generation (Including Analysis Results Metadata). This DDE app is web-based, and an intuitive way of developing SDTM and ADaM mapping specs collaboratively with version control and generates the corresponding Define.xml in real-time, which improve efficiency and quality. Other features include the easy reusability between studies, Snapshots management, Standards customization, export of Excel and Word format of define.xml for the easy review of other stakeholders.

### **INTRODUCTION**

CDISC Define.xml is data specification for submission study data. It consists of dataset level specs, variable level specs, value level specs, controlled terminology and other specs for SDTM and ADaM datasets. Its purpose is to facilitate the reviewer to quickly understand study data.

Define.xml is now mandated document for study data submission to FDA and PMDA. So, it has to be accurate and cover every details. It's an important task for clinical programmers.

Generating Define.xml efficiently and accurately now becomes a hot topic in the industry. People want a handy generating tool/system to increase the efficiency, lower the learning curve, and reduce the error rate.

### **DDE COVERS THREE MAJOR FEATURES**

#### **1. EXCEL LIKE USER INTERFACE (UI)**

Many users have the experience of using excel files for mapping specs. DDE uses Excel like UI so that users don't need spent additional time to learn this system. The tabs in DDE are like Excel sheets, and the most of columns are almost same as Excel files. For some Define.xml features such as pop-up windows for selecting controlled terms that Excel file cannot support, DDE enhances the user's experience.

With such familiar UI, users can focus more on the metadata itself and increase the working efficiency.

#### **2. LOWER THE LEARNING CURVE, AND REDUCE THE ERROR RATE IN DAILY OPERATION**

Usually users like to use Excel for mapping specs development and use SAS macros or other software like P21 to read in those mapping specs for Define.xml.

SAS macros may need additional debugging time once something goes wrong as there are complex components' relationships inside different metadata tables. It's especially difficult for SAS newbies to get the components' connection right.

Lowering the learning curving and making users at different levels to efficiently generate Define.xml in simple and familiar way can reduce the cost significantly.

#### **3. AUTOMATIC ASSISTING FUNCTION TO INCREASE EFFICIENCY**

With respect of users' habits for the flexibility of excel editing style, DDE uses additional automatic assisting function to increase the efficiency and reduce the operational redundancy.

- One click to preview Define.xml at any time, while doing metadata editing.
- Cross checking for commonly used components between different metadata tables, quickly locate to the error/issue, easy for quick fix and potentially reduce the operating error.
- Bring in the database lock concept, users can lock the metadata for Define.xml, to avoid the misoperation after all metadata ready for publish.
- Support multiple users' collaboration at same time, easy for tasks assignments and peer review.

## DESIGN PRINCIPLE

Normally one clinical study is conducted by a team of professionals with close collaboration. According to the study background and the specific requirements, this system or tool must have following features:

1. Based on Server/Client framework, to ensure the data integrity.
2. The metadata in the Define.xml, need to split into different tables, or formatted storage, in accordance to database design principles, to facilitate different format output, such as XML, Excel, or Word.
3. Easy for project management. Users can create, edit, copy, lock, and delete projects. Also bring in the snapshots function for each metadata table.
4. Support different versions of CDISC standards (Controlled Terms, SDTM and ADaM), convenient for users to manage and add custom standards, Controlled Terms, etc.
5. Simple and intuitive user interface for the operation process, which is easy for newbies to easily understand the business rules, such as the user interface for the metadata of the ADaM analysis results.
6. Support the real-time preview of the Define.xml file (one-click preview), which is convenient for users to check if the input is correct or not, and the overall progress.
7. A variety of rich assisting functions help to improve efficiency and reduce costs.
8. Support teamwork collaboration and support RESTful API to facilitate the data exchange between related systems.
9. Using the latest IT technology, stable and reliable, support in-house server deployment.

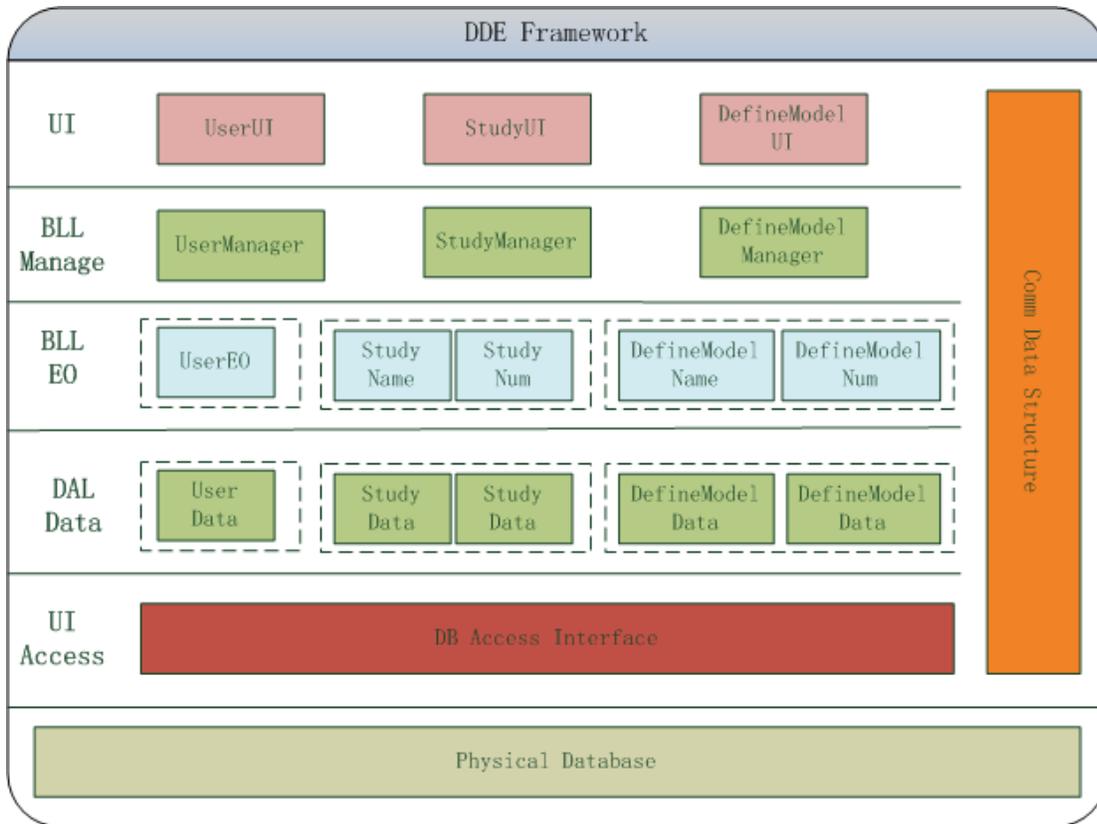
## TECHNICAL ARCHITECTURE

### 1. ARCHITECTURAL DESIGN

The system adopts the cutting-edge technology framework, based on Web 2.0 rich client solution, and connects the multi-layer architecture seamlessly.

The user edits, submits and presents information through the presentation layer (UI), and the collected data is submitted to different business processes through the business middle layer, performs data filtering, screening, formatting, etc., and performs secondary processing on the collected information. Then extract accurate information for intelligent analysis and aggregation.

### 2. THE FRAMEWORK IS ILLUSTRATED AS BELOW:



### 3. IT SUPPORT SYSTEM REQUIREMENTS

The system makes full use of the current mainstream technology platform and application practices and adopts encrypted security communication and application isolation protection technology to ensure the system is stable and reliable.

DDE supports for mainstream server platforms such as Linux and Windows. It also supports the popular Docker implementation.



## FUNCTIONAL REQUIREMENT ANALYSIS

### 1. VISUAL EXCEL STYLE EDITING USER INTERFACE (UI)

The project structure is simple and straight forward. Metadata is classified into different pieces according to Define.xml. When going into each metadata table, the interface looks like Excel, operates like Excel. Users can do copy, delete, edit and modify operation just like Excel. DDE has built-in intelligent analysis combined with bug correction function, so that users can easily jump right to those locations for bug fix.

Protocol No	Standard	Define.xml Preview	Datasets	Analysis Metadata	Datasets Description	Value Level Metadata	Controlled Terms	Reference Documents	Method Comments	Download Snapshots
Data Definitions for Demo.CDISC [copy] Owner:Andy Group: Andy 李四 张三 Tom Alisa 赵伊迪 试用账号 2019-07-11 05:06:42	SDTM		DM   EX   LB   VS   AE   DS		Edit	Edit	Edit	Edit	Method Comments	
	ADaM		ADSL   ADAE   ADQSADAS   OCCDS	Edit	Edit	Edit	Edit	Edit	Method Comments	
Data Definitions for Demo.CDISC [copy] Owner:Andy Group: ALL(Demo project) 2019-07-11 05:03:33	SDTM		DM   EX   LB   VS   AE   DS		Edit	Edit	Edit	Edit	Method Comments	
	ADaM		ADSL   ADAE   ADQSADAS   OCCDS	Edit	Edit	Edit	Edit	Edit	Method Comments	

Domain	Variable	Label	Key	Type	XmlType	Length	Controlled Terms (list)	Format	Significant Digits	ValueList Reference	Origin	CRF Page	EDC2SDTM Comments
DM	STUDYID	Study Identifier	1	Char	text	12							
DM	DOMAIN	Domain Abbreviation		Char	text	2							
DM	USUBJID	Unique Subject Identifier	2	Char	text	11							
DM	SUBJID	Subject Identifier for the Study		Char	text	4							
DM	RFSTDTC	Subject Reference Start Date/Time		Char	date	10	Category for Disposition Event				Derived		
DM	RFENDTC	Subject Reference End Date/Time		Char	date	10					Derived		
DM	RFXSTDTC	Date/Time of First Study Treatment		Char	datetime	20	Age Unit				Derived		
DM	RFXENDTC	Date/Time of Last Study Treatment		Char	datetime	20					Derived		
DM	RFICDTC	Date/Time of Informed Consent		Char	datetime	20					Derived		
DM	RFPPDTC	Date/Time of End of		Char	datetime	20					Derived		

## 2. TEAMWORK COLLABORATION

DDE supports project creators and teams to work collaboratively. It has strict access management, to facilitate task list allocation and mutual check and work coordination mechanisms.

The project creator can adjust the team members' access to view and edit the project at any time. Team members in the project team can dynamically check whether there are users in the team who are online and offline at the same time.

Protocol No	Standard	Define.xml Preview
<b>Data Definitions for Demo.CDISC</b> [copy]  Owner: Andy Group: Andy 李四 张三 Tom Alisa 赵伊迪 online 试用账号 2019-07-11 05:06:42	SDTM 	
	ADaM 	
<b>Data Definitions for Demo.CDISC</b>  Owner: Andy Group: ALL(Demo project) 试用账号 2019-07-11 05:03:33	SDTM 	
	ADaM 	

### 3. DEFINE.XML REAL-TIME GENERATION AND PREVIEW

DDE has one-click preview, supports editing and result preview real-time synchronization, quickly and efficiently renders Define.xml file.

This feature is very helpful for users to view real-time progress. This feature also verifies that all edits to the Define.xml file have been successfully completed.

Dashboard | [Data Definitions for Demo.CDISC [copy]] SDTM Define.xml Preview

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**SDTM-IG 3.2** Date of Define-XML document generation: 2019-07-21T11:25:30  
Define-XML version: 2.0.0  
Stylesheet version: 2016-07-08

[Annotated Case Report Form](#)  
[Tabulation Datasets](#)  
[Controlled Terminology](#)  
[Computational Algorithms](#)  
[Comments](#)

**Standard** SDTM-IG 3.2  
**Study Name** Data Definitions for Demo.CDISC [copy]  
**Study Description** This project is used to manipulate the demo, all data is analog data and the logic is not guaranteed.  
**Protocol Name** ISUN-CD20-2018L01  
**Metadata Name** ISUN-CD20-2018L01 Data Definition  
**Metadata Description** ISUN-CD20-2018L01 Data Definition

**Tabulation Datasets for Study Data Definitions for Demo.CDISC [copy] (SDTM-IG 3.2)**

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
DM	<a href="#">Demographics</a>	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	<a href="#">dm.xml</a>	
EX	<a href="#">Exposure</a>	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	<a href="#">ex.xml</a>	
LB	<a href="#">Laboratory Data</a>	FINDINGS	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, LBTESTCD, VISITNUM	<a href="#">lb.xml</a>	COM.DOMAIN.LB <a href="#">Complex Algorithms</a>
VS	<a href="#">Vital Signs</a>	FINDINGS	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM, VSTPTNUM	<a href="#">vs.xml</a>	
AE	<a href="#">Adverse Events</a>	EVENTS	One record per adverse event per subject	Tabulation	AETERMAESTDTC	<a href="#">ae.xml</a>	
DS	<a href="#">Disposition</a>	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	<a href="#">ds.xml</a>	

### 4. SUPPORT DIFFERENT VERSIONS OF CDISC STANDARDS

DDE supports different versions of CDISC standards (Controlled Terms, SDTM and ADaM). It can re-use metadata in the project, arbitrarily combine various metadata lists according to the selected metadata

dictionary; Users can re-use the metadata by copying the project, to reduce repetitive operations and improve editing efficiency.

Items	Contents
Study Name :	Data Definitions for Demo.CDISC [copy] *
Protocol Name :	ISUN-CD20-2018L01 *
Study Description :	This project is used to manipulate the demo, all data is analog data and the logic is not guaranteed.
Adverse Event Dictionary Name :	MedDRA Dict *
Adverse Event Dictionary Version :	4.5 *
Drug Dictionary Name :	WHODRUG *
Drug Dictionary Version :	7.1 *
SDTM Version :	V3.2 ▾
SDTM Domains :	AE,DM,DS,EX,LB,VS
⚠ Can fill in the custom SDTM	🔍
domain name	
Adam Version :	V1.0 ▾
ADaM Datasets :	ADQSADAS,ADSL,OCCDS,ADAE
⚠ Can fill in the custom ADaM	🔍
dataset name	
Controlled Terms Version :	2016-12-16 ▲

Save Cancel

## 5. SNAPSHOTS AND VERSION MANAGEMENT

Users can make snapshots of important metadata information. It's like version control of Excel mapping specs. Users can also export all metadata of the current project to Excel file for version management.

Data snapshots make it easy for users to do historical queries and rollback operations.

**[Data Definitions for Demo.CDISC [copy]] 7 Snapshot**

Datasets : All

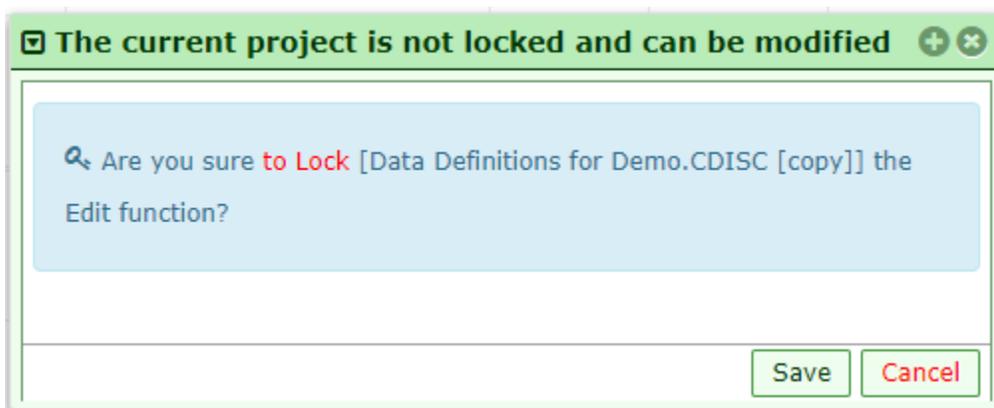
Delete	Datasets	Snapshots	Snapshots Comments	Author	Create Date
	DM	SnapShot_DM_SDTM_20190711045247	snapshot demo	john	2019-07-11 05:06:42
	AE	SnapShot_AE_SDTM_20190326112703	快照保存测试	宋新彦	2019-07-11 05:06:42
	VS	SnapShot_VS_SDTM_20190325094633	保存demo数据，整体拷贝发现ctf和vlm不能拷贝，其他集子拷贝正常。	Sam	2019-07-11 05:06:42
	LB	SnapShot_LB_SDTM_20190325093357	demo数据中拷贝过来	Sam	2019-07-11 05:06:42
	EX	SnapShot_EX_SDTM_20190325093254	demo数据中拷贝过来	Sam	2019-07-11 05:06:42
	DS	SnapShot_DS_SDTM_20190325093141	从demo数据中拷贝	Sam	2019-07-11 05:06:42
	AE	SnapShot_AE_SDTM_20190325092923	从demo数据中粘贴	Sam	2019-07-11 05:06:42

Total 7 lines Snapshots

## 6. PROJECT METADATA LOCK AND UNLOCK

The current project can be locked or unlocked for the solidification of project data for freezing and archiving.

After the project data is locked, all users in the team can only view the metadata and cannot modify or delete the operation. All the users of the team can continue to modify and edit the metadata only after the project creator unlocks the project.



## 7. CONCISE ADAM ANALYSIS RESULTS METADATA EDITING

Sometimes users may have difficulty on how to edit the ADaM analysis result metadata. DDE has established a complete editor structure through strict metadata cross-checking control.

The system visualizes and rationalizes the metadata of the ADaM analysis results, making the editing process simple and efficient, and is convenient for user to understand the business and editing operations.

Key Words :  + New Analysis Title

Analysis Results Metadata - Summary	
1	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
2	Dose response analysis for ADAS-Cog changes from baseline
3	Pairwise comparisons to placebo for ADAS-Cog changes from baseline
4	Table 14-5.02 Incidence of Treatment Emergent Serious Adverse Events by Treatment Group
5	Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

Analysis Results Metadata - Table Detail	
Display: Table 14-3.01 [page=2] Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)	
Analysis Result:	Dose response analysis for ADAS-Cog changes from baseline
Datasets:	[OCCDS]:OCCURRENCE DATA STRUCTURE
Analysis Variable(s): Dynamically change options based on Datasets	CHG
Analysis Parameter(s): Retrieve WHERECLAUSE (autofill)	PARAMCD EQ "ACTOT" (Adas-Cog(11) Subscore)
Data References (incl. Selection Criteria):	PARAMCD EQ "ACTOT" <input checked="" type="checkbox"/>
Data References for ADSL (incl. Selection Criteria), if applicable:	<input checked="" type="checkbox"/>
Programming Statements:	<pre>proc glm data = ADQSADAS;   where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ACTOT";   class SITEGR1;   model CHG = TRTPN SITEGR1; run;</pre>
Programming language (SAS/R/SPSS etc):	SAS version 9.2
Reference Document:	NA
Analysis Reason:	SPECIFIED IN SAP
Analysis Purpose:	PRIMARY OUTCOME MEASURE
Documentation:	Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose). See page 4 (section 10.1.1) in the Statistical Analysis Plan.
Reference Document:	NA
Document page number:	6

## 8. EXPORT MAPPING SPECS TO EXCEL FORMAT

User can export all metadata of the current project to the Excel file for version control, as needed at different times and different schedules.

CT controlled terms also support the direct import of excel files, which is more convenient and flexible for users.

	A	B	C	D	E	F	G	H	I
	Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation	Reference
1	TA	<a href="#">Trial Arm</a>	TRIAL DESIGN	One record per planned Element per Arm	Analysis	TAETORD, STUDYID, ARMCD,	ta.xpt		Complex
2	TE	<a href="#">Trial Elements</a>	TRIAL DESIGN	One record per planned Element	Tabulation	ETCD, STUDYID,	te.xpt		
3	TI	<a href="#">Trial Inclusion/Exclusion Criteria</a>	TRIAL DESIGN	One record per I/E criterion	Tabulation	IETESTCD, STUDYID,	ti.xpt		
4	TS	<a href="#">Trial Summary</a>	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	TSPARMCD, TSSEQ, STUDYID,	ts.xpt		
5	TV	<a href="#">Trial Visits</a>	TRIAL DESIGN	One record per Arm per planned Visit	Tabulation	ARMCD, VISITNUM, STUDYID,	tv.xpt		
6	DM	<a href="#">Demographics</a>	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID,	dm.xpt		
7	SE	<a href="#">Subject Elements</a>	SPECIAL PURPOSE	One record per actual Element per subject	Tabulation	TAETORD, USUBJID, STUDYID,	se.xpt		
8	SV	<a href="#">Subject Visits</a>	SPECIAL PURPOSE	One record per actual visit per subject	Tabulation	SVSTDC, VISITNUM, STUDYID, USUBJID,	sv.xpt		
9	CM	<a href="#">Concomitant Medications</a>	INTERVENTIONS	One record per recorded medication occurrence or	Tabulation	CMENDTC, CMSTDT, CMCAT, CMTRT, STUDYID, USUBJID,	cm.xpt		
10	EX	<a href="#">Exposure</a>	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	USUBJID, STUDYID, EXTRT, EXSTDT,	ex.xpt		
11	PR	<a href="#">Procedures</a>	INTERVENTIONS	One record per recorded procedure per occurrence per	Tabulation	PRSTDT, PRTRT, USUBJID, STUDYID,	pr.xpt		
12	SU	<a href="#">Substance Use</a>	INTERVENTIONS	One record per recorded substance use per occurrence per	Tabulation	SUFRY, SICAT, SUSPID, STUDYID, USUBJID,	su.xpt		
13	EG	<a href="#">EOC Test Results</a>	FINDINGS	One record per EOC observation per per visit per subject	Tabulation	EGDTC, VISITNUM, EGTESTCD, STUDYID, USUBJID,	eg.xpt		
14	IE	<a href="#">Inclusion/Exclusion Criteria Not Met</a>	FINDINGS	One record per inclusion/exclusion criterion	Tabulation	IECAT, IETESTCD, STUDYID, USUBJID,	ie.xpt		
15				One record per lab test per		LABDTC, LABTESTCD, USUBJID, LABCAT, STU			

## 9. SUPPORT FOR CUSTOM CDISC DOMAINS AND CT TERMS

The system not only supports the CDISC domains and CT terms in the project, but also supports custom domains and CT terms.

In addition, the system also supports editing CDISC metadata dictionaries, to fit the project needs.

NO.	Short Name	Controlled Terms	Code	Controlled Terms Data Type	Version	Data Source Type
1	AEDICT_F	MedDRA Dict		text	4.5	外库(不可追加Items)
2	AEDICT_FN	MedDRA Dict (N)		integer	4.5	外库(不可追加Items)
3	DRUGDICT_F	WHODRUG		text	7.1	外库(不可追加Items)
4	ISO3166	ISO3166		text		外库(不可追加Items)
5	LBCAT	LBCAT		text		自定义库
6	AECAUS	AECAUS		text		自定义库
7	VISITNUM	VISITNUM		text		自定义库
8	LOC	Anatomical Location	C74456	text	2016-12-16	标准库
9	NCOMPLT	Completion/Reason for Non-Completion	C66727	text	2016-12-16	标准库
10	EPOCH	Epoch	C99079	text	2016-12-16	标准库
11	ETHNIC	Ethnic Group	C66790	text	2016-12-16	标准库
12	NY	No Yes Response	C66742	text	2016-12-16	标准库
13	ND	Not Done	C66789	text	2016-12-16	标准库
14	POSITION	Position	C71148	text	2016-12-16	标准库
15	RACE	Race	C74457	text	2016-12-16	标准库
16	SEX	Sex	C66731	text	2016-12-16	标准库

Total 21 lines

## 10. MULTI-PROJECT MULTI-TAB DISPLAY AND COMPARISON

The system supports multiple metadata editing interfaces in multiple projects at the same time, which is convenient for users to consult, copy, compare, add, delete and change operations, which is convenient and flexible.

This function is commonly used in the comparative analysis of metadata for similar projects, help users to find similarities and differences, then users can copy and paste cell metadata as needed.

ID	Title	File relative path (with file name)
1	LF.acrf.001 Annotated Case Report Form	../suppdocs/acrf.pdf
2	LF.supportdoc.001 Complex Algorithms	../suppdocs/complexalgorithms.pdf
3	LF.supportdoc.002 Study Data Reviewer's Guide	../suppdocs/study-data-reviewers-guide.pdf

## 11. AUTOMATIC GENERATION OF SAS CODE FOR GENERATING DATASETS

Each data set in the project can generate relevant SAS code for download or copy to the clipboard at user's convenience.

These SAS codes are automatically generated based on the data set metadata filled out by the user.

Users can download these code files or copy the code directly to the system clipboard for easy copying and pasting.

```

[EX] Generate SAS Code
Download SAS Code Copy to Clipboard

%* Auto generated SAS Code for CDISC SDTM EX;
%* by Data Definition Editor (DDE);
%* 2019-07-21 ;

data exbase;

  attrib USUBJID label = "Unique Subject Identifier" length = $12;
  attrib DOMAIN label = "Domain Abbreviation" length = $12;
  attrib STUDYID label = "Study Identifier" length = $12;
  attrib EXTRT label = "Name of Treatment" length = 8;
  attrib EXDOSFRM label = "Dose Form" length = $8;
  attrib EXSEQ label = "Sequence Number" length = 8;
  attrib EXDOSU label = "Dose Units" length = $7;
  attrib EXDOSFRQ label = "Dosing Frequency per Interval" length = $8;
  attrib EXDOSE label = "Dose" length = 8;
  attrib VISITNUM label = "Visit Number" length = $8;
  attrib VISITDY label = "Planned Study Day of Visit" length = 8;
  attrib EXROUTE label = "Route of Administration" length = $8;
  attrib VISIT label = "Visit Name" length = $19;
  attrib EPOCH label = "Epoch" length = $9;
  attrib EXSTDTC label = "Start Date/Time of Treatment" length = $10;
  attrib EXSTDY label = "Study Day of Start of Treatment" length = 8;
  attrib EXENDTC label = "End Date/Time of Treatment" length = $10;
  attrib EXENDY label = "Study Day of End of Treatment" length = 8;

  USUBJID = "";
  DOMAIN = "";
  STUDYID = "";
  EXTRT = .;
  EXDOSFRM = "";
  EXSEQ = .;
  EXDOSU = .;
  EXDOSFRQ = .;
  EXDOSE = .;
  VISITNUM = .;
  VISITDY = .;
  EXROUTE = .;
  VISIT = .;
  EPOCH = .;
  EXSTDTC = .;
  EXSTDY = .;
  EXENDTC = .;
  EXENDY = .;

```

## 12. SUPPORT FOR RESTFUL API

DDE supports RESTful API data interface, which can seamlessly exchange related data with other systems.

The RESTful API data interface is a commonly used inter-system service data exchange technology and can also be customized to develop special interfaces according to different requirements of other systems.

## 13. CHINESE AND ENGLISH LANGUAGES FREE TO SWITCH

The system supports different two sets of user interfaces in Chinese and English, which is convenient for users to choose.



## 14. CROSS CHECK AND BUG TRACKING

DDE has built-in cross-checking between common related components, through the quick jump operation mode, helps users quickly locate the problem. Users can view the bug tracking list in real time to facilitate timely modification and adjustment.

Along each step of the user's operation, DDE performs cross-checking and bug tracking in real time. Following CDISC's definition rules for Define.xml, important logical errors will be promptly warned and marked.

NO.	Issue Type	Data Type	Message	Rule ID	Publisher ID	Description	FDA Severity	PMDA Severity	Last Checked Date
1	CodeList	SDTM	EPOCH Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06
2	CodeList	SDTM	NCOMPLT Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06
3	CodeList	SDTM	LOC Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06
4	Data Type	SDTM	Datasets EX ,EXDOSU/VSRESU CodeList/Variable Data Type mismatch	DD0080	FDAB035	Variable Data Type must match the Data Type of the referenced CodeList. Define-XML specification represents Variable as ItemDef.	Error	Warning	2019-07-14 16:13:06
5	CodeList	SDTM	ETHNIC Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06
6	CodeList	SDTM	NY Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06
7	CodeList	SDTM	ND Not quoted CodeList is not referenced	DD0082	FDAB035	Only CodeLists that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents CodeLists as CodeList elements within MetaDataVersion element.	Warning	Warning	2019-07-14 16:13:06

## SYSTEM DEPLOYMENT

According to different user requirements, Standard Edition users can directly access the DDE cloud server, which is convenient and flexible. Enterprise users can deploy the system to an in-house server for easy unified management of applications.

The system supports mainstream server platforms such as Linux and Windows, and the popular Docker containers.

## COMPARISON OF ADVANTAGES AND DISADVANTAGES

Through the comprehensive comparison with most of the related software for Define.xml generation, overall, DDE has a strong cost-effective advantage, as follows:

1. One-click preview function while in the editing operation.
2. Visual Excel editing style, automated assisting functions, cross-checking and bug tracking.
3. Online editing, unified management, support team collaboration.
4. Enterprise server deployment: support most mainstream server platforms.
5. Support project metadata locking and unlocking, metadata snapshot management.
6. Blank dataset generation SAS code is automatically generated by DDE; supports RESTful API

interface.

DDE	P21C	P21E	SAS CST	Visual Define-XML Editor	Fujitsu tsClinical Define.xml Generator
Enterprise hosted server	app	cloud server	sas macro	app	app
Group Collaboration		collabration			
Visual Operation	Excel	visual		visual	excel
Reusable components	all kinds of compliance checking	edit checks	import excel meta	open source	analysis results metadata
Data Lock		dashboard	validation		
Excel like GUI		excel like GUI			
multiple tabs for easy reference					
Sas code generator		comparisons			
DataSet Snapshots					
version control for excel mapping specs					
custom standards		custom standards	custom standards		
price reasonable	free	expensive	free	free	free
unlimited users/projects		by projects			
Data Validation Solution	no analysis results metadata		learning curve	the interface not friendly	function still has defect
			relation database	too many mouse clicks	no edit checks

## PRODUCT PLANNING

### FUTURE PRODUCT DEVELOPMENT

1. Export to Word format for easy review and comment.
2. Enhance dynamic cross-checking and bug tracking capabilities. The business and validation rules from regulatory agencies will also be implemented step by step.
3. More intelligent assisting features.

### CONCLUSION

DDE follows CDISC Define.xml standard strictly and provides effective and easy user interface. It considers the actual user operation experience and metadata contents. It increases the efficiency for generating define.xml and standardizes the operation procedures, while lowering the training cost and learning curve.

### REFERENCE

SDTM Metadata Submission Guidelines v2.0, <https://www.cdisc.org/standards/foundational/sdtm/sdtm-metadata-submission-guidelines-v20>

Pinnacle 21, <https://www.pinnacle21.com/>

SAS® Clinical Standards Toolkit (CST), <http://support.sas.com/rnd/base/cdisc/cst/index.html>

CDISC Define.xml, <https://www.cdisc.org/standards/data-exchange/define-xml>

CDISC SDTM, <https://www.cdisc.org/standards/foundational/sdtmig>

CDISC ADaM, <https://www.cdisc.org/standards/foundational/adam>

FDA Study Data Standards Resources, <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>

Visual Define-XML Editor, <https://github.com/defineEditor/editor>

Fujitsu tsClinical Define.xml Generator, <https://www.fujitsu.com/jp/solutions/industry/life-sciences/cdisc/tool/>

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