

Why don't you Define-it

Nick De Donder, Business & Decision Life Sciences, Brussels, Belgium
Anne-Sophie Bekx, Business & Decision Life Sciences, Brussels, Belgium

ABSTRACT

Define was first released by CDISC as version 1.0 in 2005 and has been an integral part of FDA submissions ever since. However, the Define.xml has greater potential than to be used for submissions only. It could potentially allow study metadata to be used for improving study design and database set-up, standardizing metadata between CROs, vendors and sponsors, it can be checked against database structure and content for validation purposes and is an integral part of any FDA submission. Indeed, in recent years BDLS has noticed that sponsors are increasingly moving towards a metadata-based approach of data management (data collection and ultimately conversion to SDTM).

In view of this, BDLS has developed the « Define-it » tool, an easy way of generating Define.xml version 1.0 and Define.xml version 2.0 from study specifications, and of converting Define.xml version 1.0 to Define.xml version 2.0.

INTRODUCTION

Define was first released by CDISC as version 1.0 in 2005 and has been an integral part of FDA submissions ever since. In March of this year version 2.0 was released for use in FDA submissions. However, the Define.xml has greater potential than to be used for submissions only. Firstly, it contains 5 levels of metadata that make up a study metadata, allowing metadata repository build. Define.xml could therefore potentially allow study metadata to be used for improving study design and database set-up, standardizing metadata between CROs, vendors and sponsors, it can be checked against database structure and content for validation purposes and is an integral part of any FDA submission. Indeed, in recent years BDLS has noticed that sponsors are increasingly moving towards a metadata-based approach of data management (data collection and ultimately conversion to SDTM).

In addition, in March of this year, CDISC released Define.xml version 2.0 in which the metadata submission model has been extensively refined in response to implementation experience with version 1.0, evolution of the standards, and best practices by metadata experts. Major changes include flexible definitions of VLM, XML namespacing aligned with the ODM 1.3.1 standard, enhanced handling of comments and better support for split domains. The FDA have put out an official release that they will be accepting Define 2.0 as of August 15th 2013

In view of this, BDLS has developed the « Define-it » tool, an easy way of generating Define.xml version 1.0 and Define.xml version 2.0 from study specifications, and of converting Define.xml version 1.0 to Define.xml version 2.0.

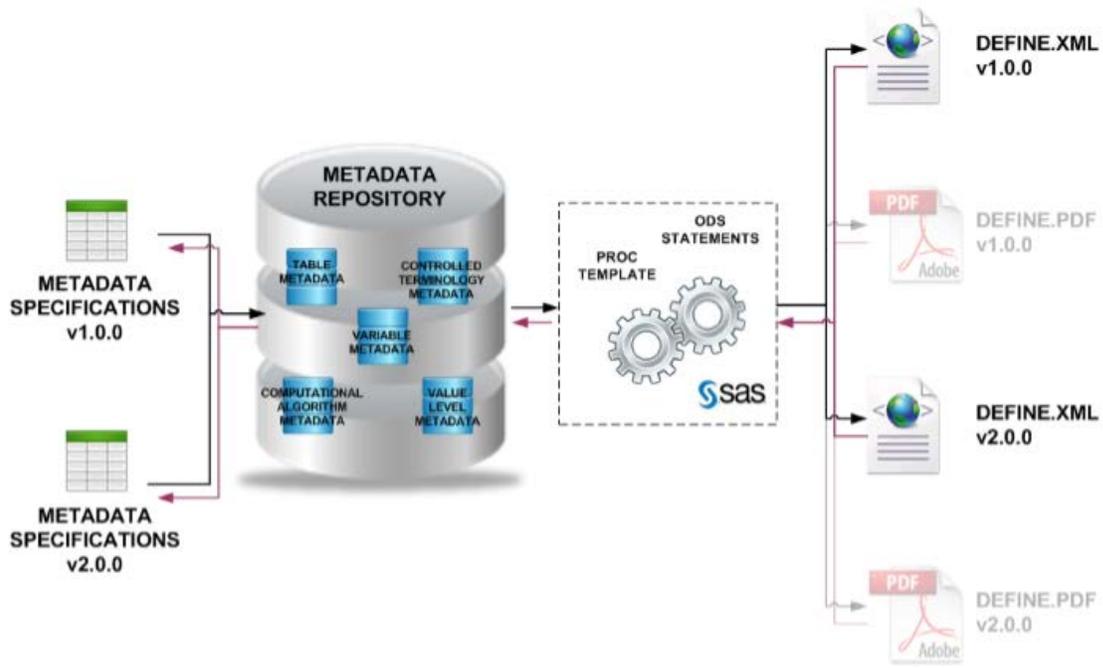


Figure 1: Define-it overview

The tool reads metadata specifications in Excel format, loads them into a metadata repository and applies SAS ODS statements to generate Define.xml.

Its benefits include providing fully CDISC compliant deliverables, a SAS and XML based solution which makes it a proven technology, a user-friendly solution, and a highly customizable solution.

DEFINE-IT

SYSTEM REQUIREMENTS

The Define-it tool is made in Java and uses SAS to process and generate the metadata specifications and the define.xml. To be able to run this application, your system must have the following installed:

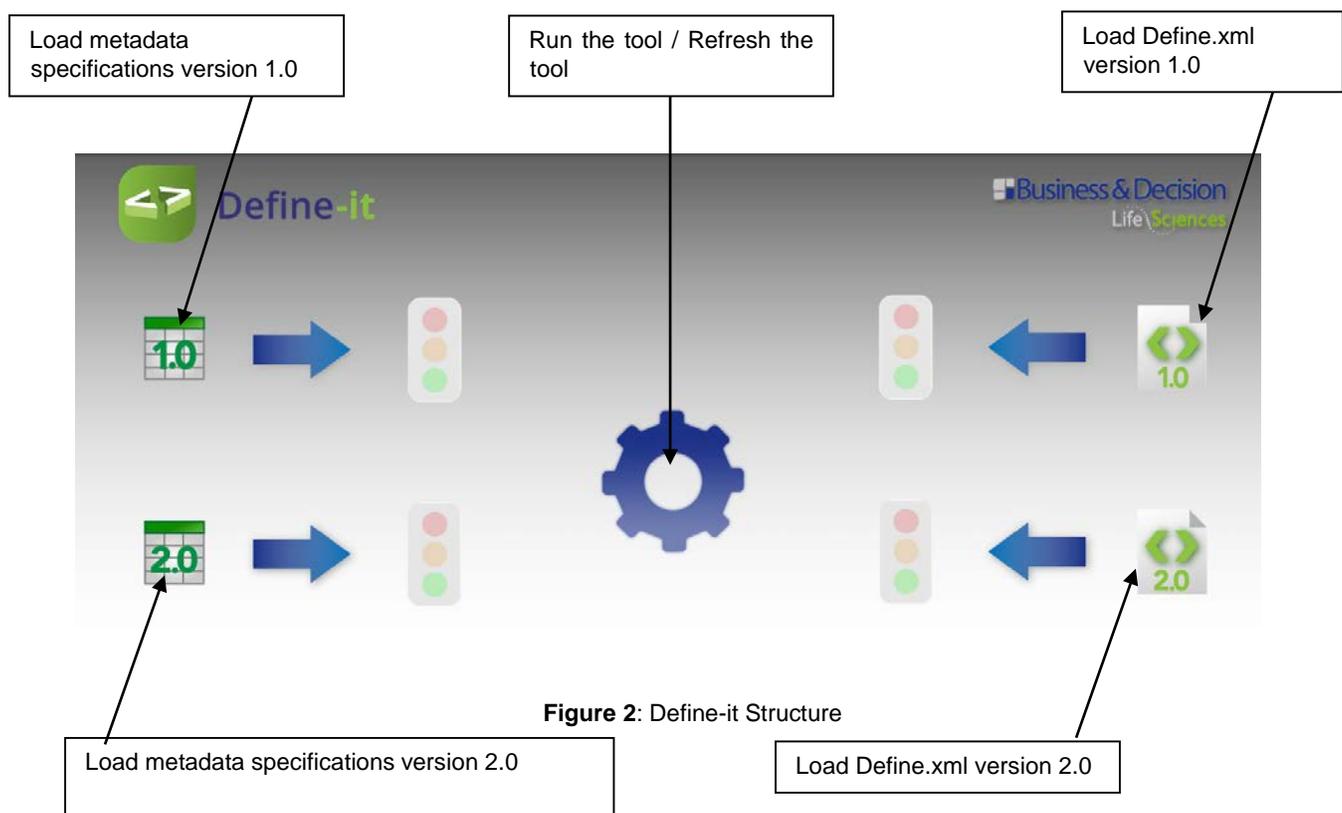
- SAS 9.2 or higher
 - SAS foundation
 - SAS/ACCESS to pc files
- Windows XP/ME/2000/Vista/7/8 32-bit or 64-bit
- Java 1.6 or higher

RESTRICTIONS

- The stand-alone version of Define-it is meant for a single user per product. This means the tool will only work on desktop computers. The Enterprise version is available to host Define-it on a web-server, which is multi-user.
- To ensure a good SAS process, please make sure no SAS instances are open while using the tool.

STRUCTURE

The Define-it tool is made of 5 buttons with 5 distinct functionalities as shown in the screenshot below:



GENERATING A DEFINE.XML

METADATA SPECIFICATIONS

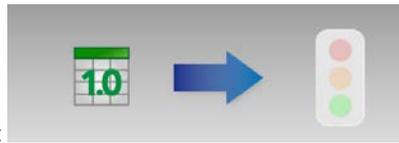
A define.xml file, version 1.0 or version 2.0, is generated by loading metadata specifications, version 1.0 or version 2.0, into the tool.

Metadata specifications are in the form of an Excel file and list the 5 levels of metadata, as well as all information regarding the XML parameters, as shown by the example below in **Figure 3**.

A	B	C	D	E	F
Dataset	Description	Class	Structure	Purpose	Keys
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AETERM, AESTDTC
CM	Concomitant Medications	INTERVENTIONS	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMCAT, CMSTDTC
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID
SUPPAE	Supplemental Qualifiers for AE	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
VS	Vital Signs	FINDINGS	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM, VSDTC

Figure 3: Metadata Specifications example

RUNNING THE TOOL



Click on the button on the top left

to load metadata specifications version 1.0.

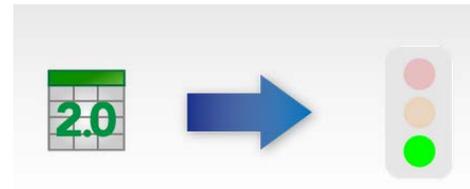
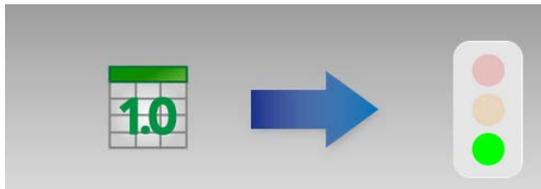


Click on the button on the bottom left

to load metadata specifications version 2.0.

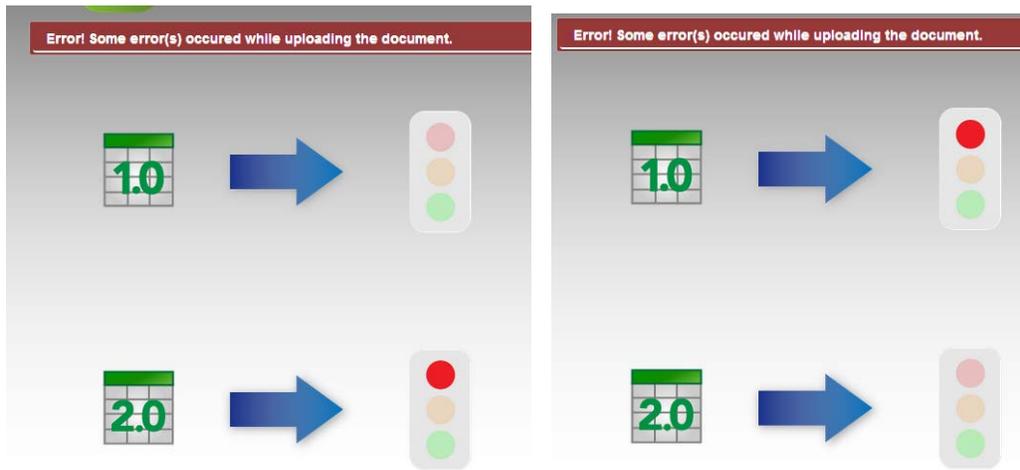
The wheel in the middle turns as long as the program is running.

When the program is finished, a green light appears to notify the user that the metadata specifications were uploaded successfully.



If an error occurs and specifications are not loaded properly, a red light appears to notify the user of any issues.

The error line can be expanded by clicking on its top right corner to see a complete list of all error messages recorded by the tool.



If metadata specifications version 1.0 were uploaded, the corresponding Define.xml version 1.0 can be downloaded



as a zip file by clicking on the button on the top right.

If metadata specifications version 2.0 were uploaded, the corresponding Define.xml version 2.0 can be downloaded



as a zip file by clicking on the button on the bottom right.

Please note that in order to open the Define.xml files, they need to be extracted from the zip files.

GENERATING METADATA SPECIFICATIONS

DEFINE.XML

Metadata specifications, version 1.0 or version 2.0, are generated by loading a define.xml file, version 1.0 or version 2.0, into the tool.

The wheel in the middle will turn while the program is running.

Define.xml are ODM compliant files listing the 5 levels of metadata

RUNNING THE TOOL



Click on the button on the top right to load Define.xml version 1.0.



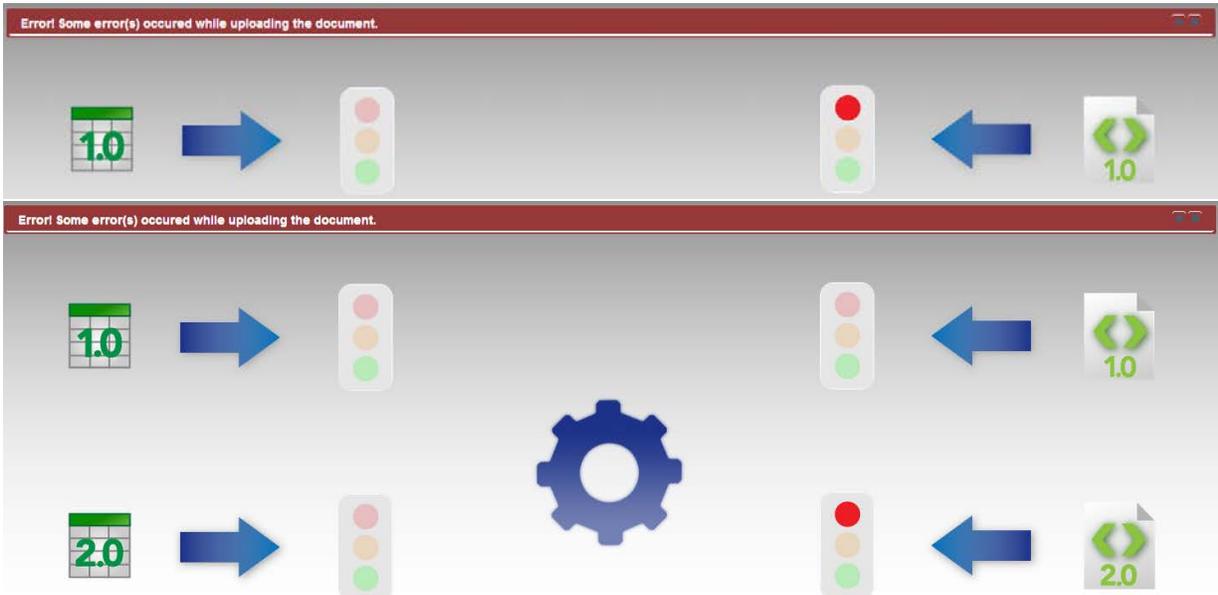
Click on the button on the bottom right to load Define.xml version 2.0.

The wheel in the middle turns as long as the program is running.

When the program is finished, a green light appears to notify the user that the define file was uploaded successfully.



If an error occurs and define.xml files are not loaded properly, a red light appears to notify the user of any issues. The error line can be expanded by clicking on its top right corner to see a complete list of all error messages recorded by the tool.



If a Define.xml version 1.0 was uploaded, the corresponding metadata specifications version 1.0 can be downloaded



by clicking on the button on the top left,

If a Define.xml version 2.0 was uploaded, the corresponding metadata specifications version 2.0 can be downloaded



by clicking on the button on button on the bottom left,

CONCLUSION

The application contains the following key features:

- Generate Define.xml v1 and v2 from metadata specifications
- Convert Define.xml v2 to Define.xml v1
- Convert Define.xml v1 and v2 into metadata specifications,

It hereby provides the following benefits:

- Deliverables that are fully CDISC compliant
- A proven technology
 - the Define-It solution is SAS and XML based
- A user friendly solution
- A highly customizable solution

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Anne-Sophie Bekx
Business & Decision Life Sciences
141, Rue Saint-Lambert
1200, Bruxelles
Belgium
Work: 0032 2 774 1100
Fax: 0032 2 774 1199
Email: anne-sophie.bekx@businessdecision.com

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