



CDISC 2020 Europe Interchange

Virtual Conference

1-2 April 2020



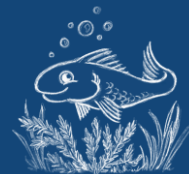
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- The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Open Source for CDISC – What? Why? How?

Presented by Katja Glaß
Katja Glass Consulting, Berlin, Germany

2. April



Katja has more than 14 year experiences in SAS programming within the pharmaceutical industry. She focus her consulting activities to bring more open source to our industry.



Agenda

1. Introduction
2. Available Solutions
3. Advantages & Challenges
4. Opportunities
5. Summary



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Consulting

Introduction

What is Open Source about?

Introduction



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Definition:

Open Source software is software that can be freely accessed, used, changed, and shared (in modified or unmodified form) by anyone.

(<https://opensource.org/faq#osd>)

- Compared to “free” software + full transparency
- Licenses matter (how to make further use)





Introduction

Usage:

- Web Development (bootstrap, JQuery, ...)
- Developer IDEs (Eclipse, Atom, ...)
- Operating System (Unix, Android, ...)
- Tools, Applications, Source Code

Need it for:

- Clinical Study Evaluations & Related Tasks



Available Solutions

What is available to support CDISC processes?



Available Solutions

- Pinnacle21 Community Edition
... but what else???

Issue:

- Finding solutions!
- Open Source Portal
for clinical study evaluations
www.glacon.eu/portal

The screenshot shows the Katja Glass Consulting website with a purple header. The main content area is divided into three columns, each featuring a different tool:

- FDA Jumpstart Scripts**: Clinical study evaluations scripts used by the FDA in their JumpStart tool. The FDA contributed the JumpStart SAS scripts so these are available on the PhUSE repository for use. It includes a table with columns: Study, Version, Date, and Status. The table shows several entries for different studies and versions.
- RPact**: The R package RPACT is a statistical program module, characterized as a comprehensive, validated software R package, that enables the simulation and analysis of parallel group designs with continuous, binary, and survival endpoint. RPACT can be downloaded per CRAN and will be available as open-source under LGPL3.
- Visual Define-XML Editor**: A cross-platform desktop application which allows to edit and review Define-XML files in a convenient and efficient way. It fully supports CDISC Define-XML v2.0 and ARM 1.0 standards.

At the bottom of the page, there are links to "SAS Scripts", "Outputs", "R Tool", and "Statistics".



Available Solutions

Searching for “CDISC”

- Pinnacle21 Community Edition
- Visual Define-XML Editor
- R4DSXML
- Smart Submission Dataset Viewer

Also available:

- Evaluation Scripts (FDA Jumpstart)
- General SAS Macros
- Whitepaper Scripts

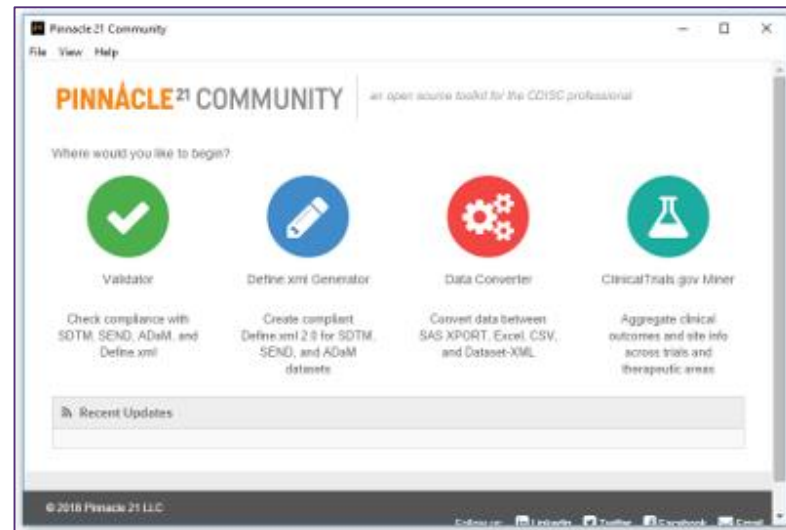
Visual Table	
Name	Description
<input type="text"/>	<input type="text" value="CDISC"/>
Visual Define-XML Editor	A cross-platform desk...
Pinnacle21 Community Edition	This tool supports vari...
R4DSXML	R4DSXML is R packag...
Smart Submission Dataset Viewer	Smart Submission Dat...

Available Solutions



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- Pinnacle21 Community Edition
 - Language: Java
 - Broadly used
 - Common understanding
 - Easy exchange
 - Restricting license
 - Additional unpublic packages

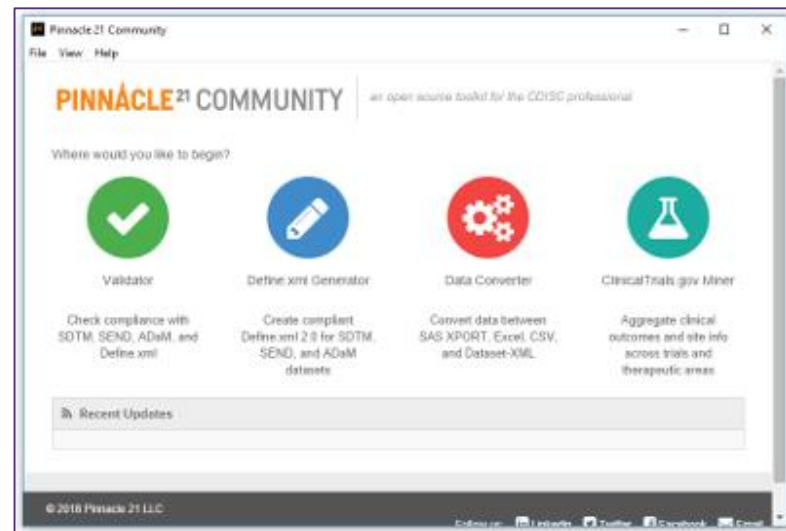


Available Solutions



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- Pinnacle21 Community Edition
 - Language: Java
 - Broadly used
 - Common understanding
 - Easy exchange
 - Restricting license
 - Additional unpublic packages
- Similar free tools
 - SAS® Clinical Standards Toolkit
 - MySEND (also for ADAM & SDTM)



Available Solutions



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- Visual define.xml Editor (<http://defineeditor.com>)
 - Language: JavaScript / HTML
 - By Dmitry Kolosov & Sergei Krivtsov
 - Edit define.xml
 - AGPL 3.0 license

The screenshot displays the 'Visual Define-XML Editor' window. The top navigation bar includes tabs for DATASETS, VARIABLES, CODELISTS, CODED VALUES, DOCUMENTS, ARM SUMMARY, and ANALYSIS RESULTS. The 'ANALYSIS RESULTS' tab is active, showing a table configuration for 'Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)'. Below the table title, there is an 'ADD ANALYSIS RESULT' button and a 'CE' icon. The table configuration is divided into several sections: 'Description' (Dose response analysis for ADAS-Cog changes from baseline), 'Analysis Reason' (Specified in SAP), 'Analysis Purpose' (Primary Outcome Measure), and 'Parameter' (ADQSADAS.PARAMCD). Below these, there is a 'Datasets Comment' section with a plus icon, a 'Datasets' section with a plus icon and a list of datasets (ADQSADAS), and a 'Selection Criteria' section with a plus icon and a list of criteria (PARAMCD EQ "ACTOT" AND AVISIT EQ "Week 24" AND EFFFLEQ EQ "Y" AND ANL01FLEQ EQ "Y"). At the bottom, there is an 'Analysis Variables' section with a plus icon and a list of variables (CHG (Change from Baseline)).



Available Solutions

- R4DSXML
 - Import CDISC Dataset-XML and Define-XML into R DataFrame

Filter					
IR_ItemOID	IGD_Name	IR_OrderNumber	IR_Mandatory	IR_Key	
1 IT.ADQSADAS.STUDYID	ADQSADAS		1 No		
2 IT.ADQSADAS.SITEID	ADQSADAS		2 No		
3 IT.ADQSADAS.SITEGR1	ADQSADAS		3 No		
4 IT.ADQSADAS.USUBJID	ADQSADAS		4 No		
5 IT.ADQSADAS.TRISDT	ADQSADAS		5 No		
6 IT.ADQSADAS.TRTEEDT	ADQSADAS		6 No		
7 IT.ADQSADAS.TRTP	ADQSADAS		7 No		
8 IT.ADQSADAS.TRTPN	ADQSADAS		8 No		
9 IT.ADQSADAS.AGE	ADQSADAS		9 No		
10 IT.ADQSADAS.AGEGR1	ADQSADAS		10 No		
11 IT.ADQSADAS.AGEGR1N	ADQSADAS		11 No		
12 IT.ADQSADAS.RACE	ADQSADAS		12 No		
13 IT.ADQSADAS.RACEN	ADQSADAS		13 No		
14 IT.ADQSADAS.SEX	ADQSADAS		14 No		
15 IT.ADQSADAS.ITTFL	ADQSADAS		15 No		

```
library(R4DSXML)
library(testthat)

## Test metadata preparation
define <- system.file("extdata",
                      "ADaM",
                      "define2-0-0-example-adam.xml",
                      package="R4DSXML")

#Get dataset level metadata
dataset.metadata <- getDLMD(define)

#Get variable level metadata
variable.metadata <- getVarMD(define)

#Get value level metadata
value.metadata <- getValMD(define)

#Get Controlled Terminology
ct.metadata <- getCT(define)
```

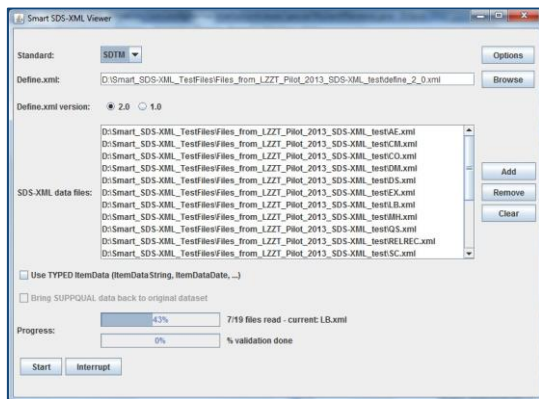
NA	ITTFL	1	NA	text
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Available Solutions



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- Smart Submission Dataset Viewer
 - View CDISC submission files in Dataset-XML format
 - Implementing CDISC Library API
 - By XML4Pharma
 - MIT License



DM	RELREC	CO	AE	CM	DS	EX	LB	MH	QS	SC	SE	SV	TA	TE	TI	TS	TV	VS
STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDT	RFENDT	RFXSTDT	RFXENDT	RFICDT	RFPENDT									
CDISCIPIL...	DM	01-701-1015	1015				2014-01-02	2014-07-02	2014-01-02	2014-07-02								2014-07-0
CDISCIPIL...	DM	01-701-1023	1023				2012-08-05	2012-09-0a	2012-08-02	2012-09-01								2013-02-1
CDISCIPIL...	DM	01-701-1028	1028				2013-07-19	2014-01-14	2013-07-19	2014-01-14								2014-01-1
CDISCIPIL...	DM	01-701-1033	1033				2014-03-18	2014-04-14	2014-03-18	2014-03-31								2014-09-1
CDISCIPIL...	DM	01-701-1034	1034				2014-07-01	2014-12-30	2014-07-01	2014-12-30								2014-12-3
CDISCIPIL...	DM	01-701-1047	1047				2013-02-12	2013-03-32	2013-02-12	2013-03-09								2013-07-2
CDISCIPIL...	DM	01-701-1057	1057															2013-12-2
CDISCIPIL...	DM	01-701-1097	1097				2014-01-01	2014-07-09	2014-01-01	2014-07-09								2014-07-0
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CDISCIPIL...	DM	01-701-1118	1118				2014-03-12	2014-09-09	2014-03-12	2014-09-09								2014-09-0
CDISCIPIL...	DM	01-701-1130	1130				2014-02-15	2014-08-16	2014-02-15	2014-08-16								2014-08-1
CDISCIPIL...	DM	01-701-1133	1133				2012-10-28	2013-04-29	2012-10-28	2013-04-28								2013-04-2
CDISCIPIL...	DM	01-701-1145	1145															2013-09-1
CDISCIPIL...	DM	01-701-1146	1146				2013-05-20	2013-06-30	2013-05-20	2013-06-26								2013-07-1
CDISCIPIL...	DM	01-701-1148	1148				2013-08-23	2014-02-20	2013-08-23	2014-02-20								2014-02-2
CDISCIPIL...	DM	01-701-1162	1162															2014-04-0
CDISCIPIL...	DM	01-701-1162	1162															2013-04-1
CDISCIPIL...	DM	01-701-1176	1176															2012-09-3
CDISCIPIL...	DM	01-701-1180	1180				2013-02-12	2013-03-23	2013-02-12	2013-03-18								2013-04-0
CDISCIPIL...	DM	01-701-1181	1181				2013-12-05	2013-12-12	2013-12-05	2013-12-09								2014-05-2
CDISCIPIL...	DM	01-701-1188	1188				2013-02-15	2013-03-25	2013-02-15	2013-03-24								2013-08-0
CDISCIPIL...	DM	01-701-1192	1192				2012-07-22	2013-01-20	2012-07-22	2013-01-20								2013-01-2
CDISCIPIL...	DM	01-701-1203	1203				2013-02-02	2013-08-03	2013-02-02	2013-08-03								2013-08-0
CDISCIPIL...	DM	01-701-1211	1211				2012-11-15	2013-01-14	2012-11-15	2013-01-12								2013-01-1
CDISCIPIL...	DM	01-701-1234	1234				2013-03-30	2013-09-22	2013-03-30	2013-09-22								2013-09-2
CDISCIPIL...	DM	01-701-1239	1239				2014-01-11	2014-07-11	2014-01-11	2014-07-10								2014-07-1
CDISCIPIL...	DM		1240															2013-09-2

Available Solutions



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- Additional Mentioning

- PhUSE Updated CDISC Pilot Data
- SEND Data Factory
- CLI Define.xml Tools
- A3 Community MDR - Browse CDISC CTs (partly free tool, no open source)
- Reindeer – Render SAS Results into Word





Advantages & Challenges

Why should we do open source?

What to consider?

Advantages & Challenges



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Advantages

- Development Speed
- Technology Flexibility
- Total Cost of Ownership
- Functionality
- Developer Satisfaction
- Quality of Code
- Performance & Stability

Speed, Flexibility and Lower Costs are Top Benefits of Using Open Source



Source: "Open Source Programs in the Enterprise - 2019" Survey.

Q: Of the following options, what are the top three benefits your company receives by using open source software? n=1643.



<https://github.com/todogroup/survey/tree/master/2019>

Advantages & Challenges

Advantages

- Cheaper
 - Overall development costs
 - Training
- More Robust
 - Auditable
 - More eyes -> less bugs
 - More brains -> better solutions
- Create common processes



Advantages & Challenges



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Challenges

- Communication
- Documentation
- Training
- Validation
- Financing
- ...





Advantages & Challenges

Why is Open Source created?

- Motivation
 - Personal Engagement, Working Groups, Communities
- + Functionality
 - Documentation
 - Training
 - Validation



Advantages & Challenges

Why is Open Source created?

- Professionalism
 - Visibility of Knowledge, “Attraction” of a CRO

- + Functionality
- + Documentation
- Training
- Validation





Advantages & Challenges

Why is Open Source created?

- Business
 - Making further Business (limited functionality, additional contracts, funding, sponsorship...)
- + Functionality
- + Documentation
- (-) Training
- (-) Validation



Advantages & Challenges

Open Source in Pharma?

- Benefit mainly for huge companies
- No use-case “outside”
- Motivation low
- Business looking for local advantages





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Opportunities

How to enable more open source?

What could the future be?



Opportunities

Use Solutions

- Download & use
 - Functionality to go
 - Learning by watching
 - Functionality as building blocks for more complex tools
- Depending on license, easy





Opportunities

Get More Solutions

- Allow employees & contractors to publish open source
- Join open collaborations
- Invest in open source





Opportunities

- Allowance -> less worries
 - General approval
 - Approval process
- Collaborations / working groups
 - Provide enough time
 - Engage in documentation
- Investments
 - Enables any kind of Open Source



Opportunities

Why Investments?

- Where would CDISC be without financing?
- Who would do detailed documentation?
- What is the status of collaboration / working groups without financing?



Opportunities

Where could investments lead to?

- Financing for Working Groups
 - Enriched documentation
 - Faster processes
 - Public implementations
- Financed Collaborations
 - Example: RPact
 - Multiple companies sponsor Open Source Software
 - Free for all, extras (validation documentation etc.) for members





Opportunities

Where could investments lead to?

- Single Open Source Project Financing
 - Small budget prototypes
 - Follow up products

Choose a “free” license, e.g. MIT

- Avoid too strong commercializing



Opportunities



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Solutions for Everything behind every corner!

CDISC
Mapping
Framework

Various
Define
Tools

CDISC Version
Management

Traceability
Matrix

End-to-End
Support

213

...

Public
Free
Trainings



Opportunities

High Open Source Quality is not for free

- Commercial development and maintenance
- Especially in Pharma
 - Time pressure
 - High quality & validation needs
- Still high-benefit





Summary

Open Source is available!

Much more is needed!

Summary



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- Checkout what is available (www.glacon.eu/portal)
- Try out and apply solutions
- **Enable more open source**
 - Allow employees & contractors to publish open source
 - Join open collaborations
 - Invest in open source





Summary

Think Abouts

- What did Pinnacle21 Community showed us?
- What if we have more solutions?
- Financing could enable what WE want (e.g. MIT licensed open source)
- High quality typically needs financing

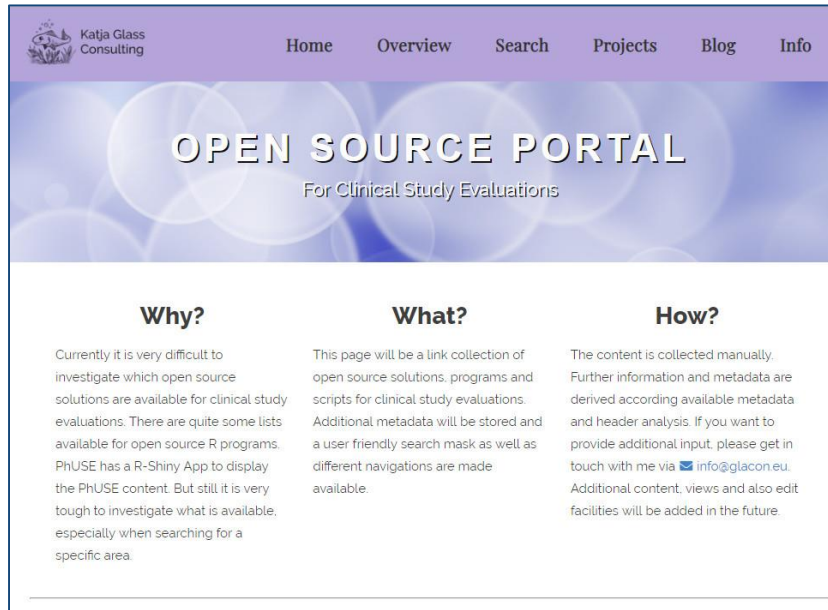
Summary



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More Information

- Katja Glass Consulting @YouTube
- Open Source Portal
(www.glacon.eu/portal)
- Open Source Guides
(<https://opensource.guide/>)





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Thank You!

