

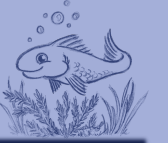
Katja Glass
Consulting

Open Source for Pharma

Solutions, Challenges
and Visions



Agenda



Introduction

Solutions

Challenges

Visions

Summary



Introduction



- Collaborations are key nowadays
 - Open Source
 - Functionality to Go
 - Reusable (don't reinvent the wheel)
 - Common Understanding
 - Learning
-

Introduction



- Open Source FAIR for Scripts
 - Findable
 - Accessible
 - (Interoperable)
 - Re-usable
-

Introduction



- Open Source FAIR for Scripts
 - Findable
 - Accessible
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 - Re-usable



CRAN

(Comprehensive R Archive
Network)

```
install.packages("phuse")
```

Introduction



- Open Source FAIR for Scripts
 - Findable
 - Accessible
 - (Interoperable)
 - Re-usable



CONDA
(package manager)

JavaScript

NPM / YARN
(package manager)

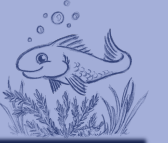
Introduction



- Open Source FAIR for Scripts
 - Findable
 - Accessible
 - (Interoperable)
 - Re-usable

SAS®

Agenda



Introduction

Solutions

Challenges

Visions

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Solutions



- Many R Packages available
 - List of Packages for ClinicalTrials
(<https://cran.r-project.org/web/views/ClinicalTrials.html>)
 - RPact - Adaptive Clinical Trials
 - Shiny
 - Mediana R Package - Clinical trial optimization using R
 - Master & Doctor theses implementations
 - Officer for docx and pptx
 - RTable from Roche
 - ...



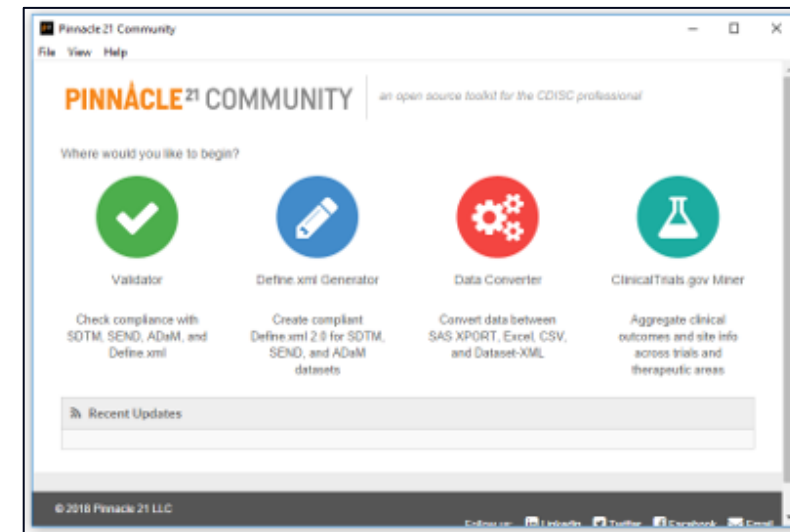
Can R be used in
Clinical Study Evaluations?

(<https://www.slideshare.net/AdrianOlszewski1/gnu-r-in-clinical-research-and-evidencebased-medicine>)

Solutions



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



Solutions



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

Visual Define-XML Editor

2 < DATASETS VARIABLES CODELISTS CODED VALUES DOCUMENTS ARM SUMMARY ANALYSIS RESULTS

Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)

ADD ANALYSIS RESULT

Description
Dose response analysis for ADAS-Cog changes from baseline

Analysis Reason
Specified in SAP

Analysis Purpose
Primary Outcome Measure

Parameter
ADQSADAS.PARAMCD

Datasets Comment

Datasets
Dataset
ADQSADAS

Selection Criteria
PARAMCD EQ "ACTOT" AND AVISIT EQ "Week 24" AND EFFFLEQ EQ "Y" AND ANL01FL EQ "Y"

Analysis Variables
CHG (Change from Baseline)

Solutions



- SAS Macros by Scott Bass (<https://github.com/scottbass/SAS>)
 - Small useful SAS Macros
 - MIT license (free for anything)

SAS®

%Compare

%LogParse

%Excel2SAS

Solutions



SAS®

- SAS Macros by Boemska
 - Source (<https://github.com/Boemska/macrocore>)
 - Documentation (<https://boemska.github.io/macrocore.github.io/>)
 - MIT license (free for anything)

`%mf_mkdir`

`%mf_getVarCount`

`%mp_dirlist`

Solutions



SAS®

- SASUnit supported by HMS
 - SAS Validation Framework
 - Source & Documentation (<https://sourceforge.net/projects/sasunit/>)
 - GPLv3 license

The screenshot displays the SASUnit Examples web interface. The left sidebar shows a tree view of test scenarios, with 'saspgm/nobs_test.sas' selected. The main content area shows the details for scenario 010, 'Tests for nobs.sas - has to fail!'. Below this, a table lists the test cases and their results.

No.	Test Case	Unit under Test	Last Run	Duration	Result
001	simple example with sashelp.class	nobs.sas	12JUL2017:10:19:14	0.1 s	✓
002	failed test - must be red!	nobs.sas	12JUL2017:10:19:15	0.1 s	✗
003	example with big dataset	nobs.sas	12JUL2017:10:19:15	0.3 s	✓
004	example with empty dataset	nobs.sas	12JUL2017:10:19:15	0.1 s	✓
005	dataset not specified	nobs.sas	12JUL2017:10:19:15	0.1 s	✓
006	invalid dataset	nobs.sas	12JUL2017:10:19:16	0.1 s	✓

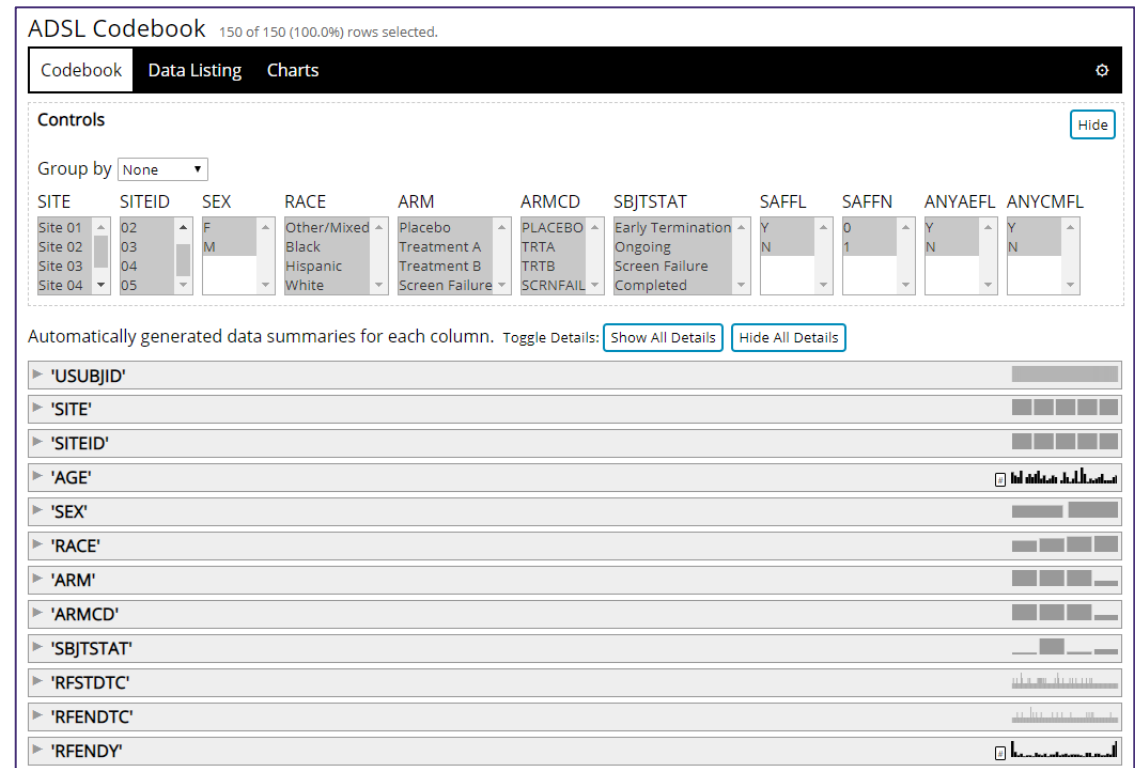
Below the first table, the details for scenario 011, 'Tests showing program documentation features', are shown. A second table lists the test cases for this scenario.

No.	Test Case	Unit under Test	Last Run	Duration	Result
001	Showing program documentation features	ProgramDocumentationDummy.sas	12JUL2017:10:19:17	0.1 s	✓

Solutions



- Web Codebook (<https://github.com/RhoInc/web-codebook>)
 - Language: JavaScript / HTML
 - By RhoInc
 - Interactive Data Visualization



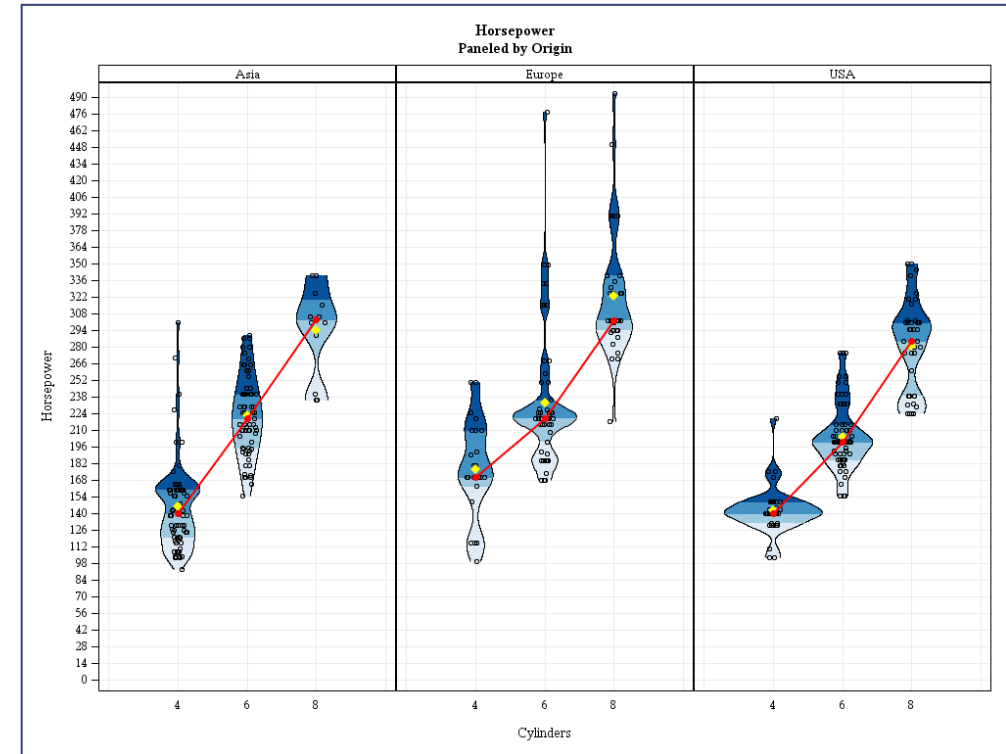
Solutions



SAS®

- Multiple Graphics & Other Scripts by RhoInc
 - Violin Plot, Sankey Style Barchar, Bee Swarm Plot, ...
 - Source (<https://github.com/RhoInc>)
 - MIT license (free for anything)

JavaScript



Solutions



- PhUSE Scripts (<https://github.com/phuse-org/phuse-scripts>)

- JumpStart FDA Scripts
- Scripts creating whitepaper outputs
- General other scripts

SAS®



- PhUSE Project Scripts

- Linked Data scripts (<https://github.com/phuse-org/CTDasRDF>)
- SEND Data Factory
- ...



Solutions

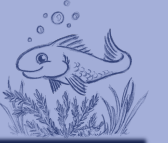


SAS®

- Hidden Jewels
 - SAS™ Support Pages
 - Papers
 - Community Lists (SAS-L, Stackoverflow, ...)



Agenda



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Solutions

Challenges

Visions

Summary



Challenges



User Perspective

Functionality

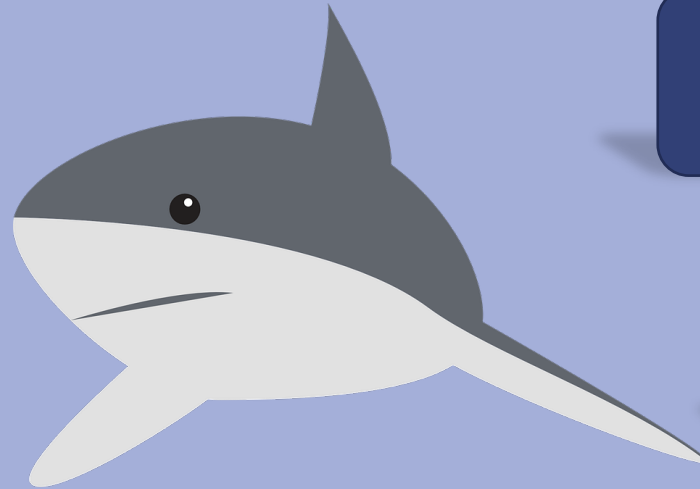
Validation

Documentation

Support

Training

Maintenance

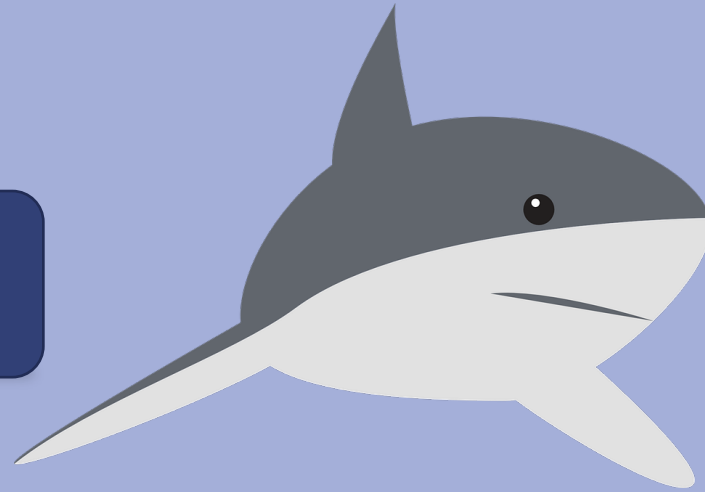


Challenges



Developer Perspective

Legal



Time
Management

Support
Handling

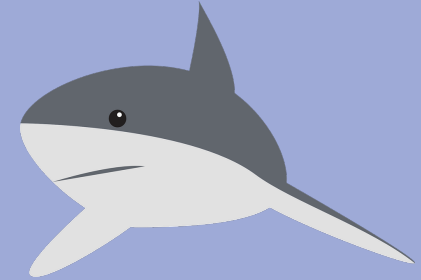
Financing

Challenges



- What is the project about?
- Project status?
- How to use?
- Requirements?

Documentation



- Why do people do things?

Motivation

Goal

Money

Challenges



➤ PhUSE Collaboration Projects

Motivation

Business Need

Functionality

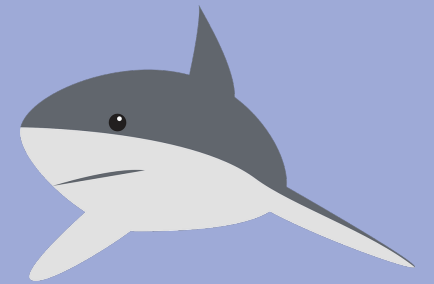
Maintenance

Documentation

Support

Training

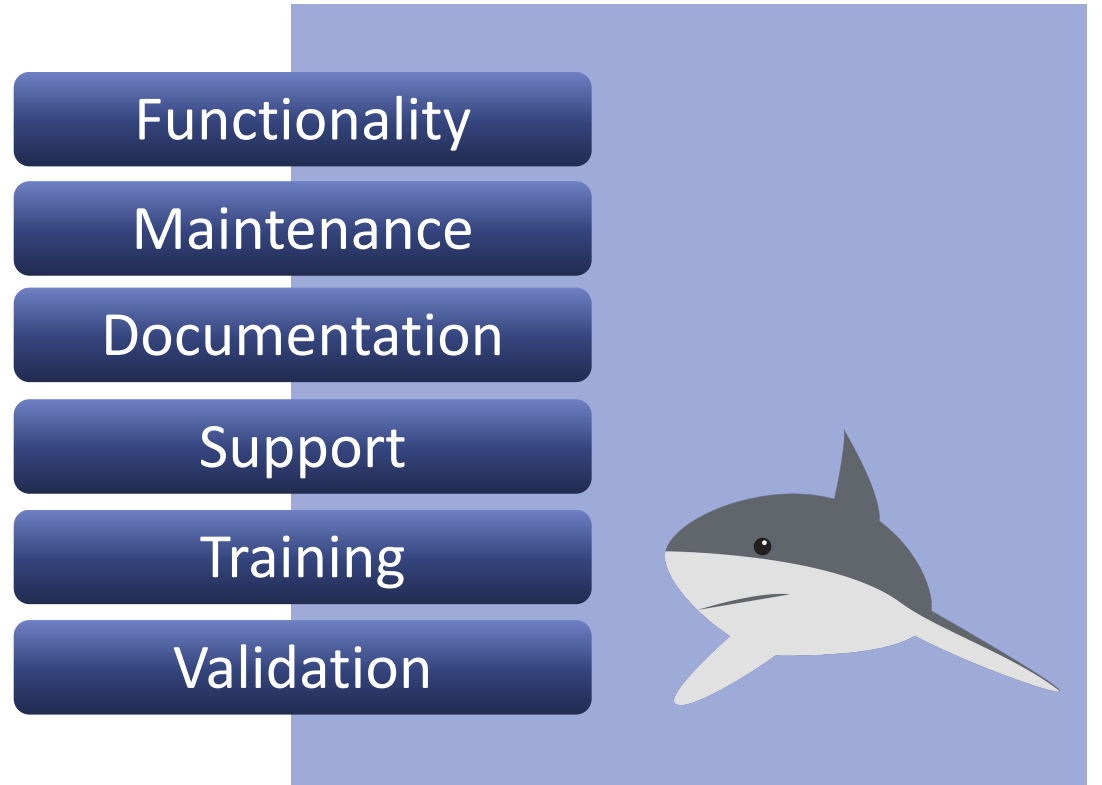
Validation



Challenges



➤ Pinnacle21 Community Edition



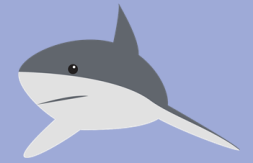
Challenges



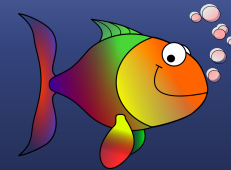
➤ RPact

- Companies made a pact
- Financing project through membership
- All functionality & maintenance open
- Basic documentation open
- Additional services only for members
 - Enhanced Training
 - Priority Support
 - Training
 - Validation Documentation

Functionality
Maintenance
Documentation
Support
Training
Validation



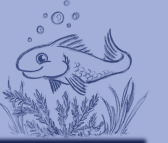
Financing



Time Management

Support Handling

Agenda



Introduction

Solutions

Challenges

Visions

Summary



Visions



➤ Solutions for Everything behind every corner!

Evaluation
Scripts

OnBording
Classes

Graphic
creation

Mapping
Framework

Machine
Learning
insights

Interactive
Vizualization

Script/Macro
Management

Trends &
Technologies

Visions



- Open up at companies
 - Enable & support open source
 - Allow contractors to release source
 - Publish students work
 - Join & support PhUSE working groups

Legal

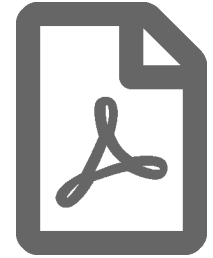


Visions



- Documentation is important!
 - Just do it
 - Try to motivate for documentation
 - Hire people for documenting

- Collaboration is important!
 - Authorities does not want single per-company solutions!
 - Build up together! Don't exclude academia or small companies!



Visions



- New Open Source Finance Concepts
 - Support Open Source through
 - Donations
 - Sponsorship
 - Funding

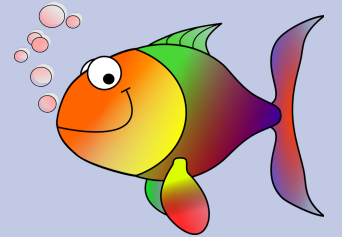
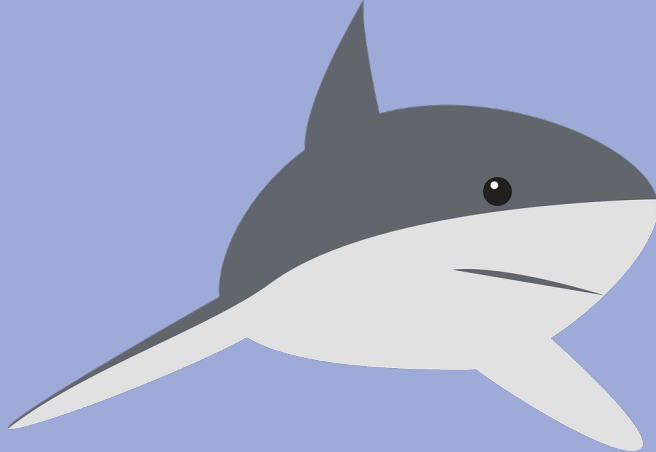
- Create “Pacts” to follow common goals, **OPEN**



Visions



- Silicon Valley
 - 70 – 95% of startups fail
 - 5-30% becoming a success is enough



Visions



➤ FAIR

➤ Findable - Open Source Portal

➤ www.glacon.eu/portal

➤ Accessible – CRAN like download platform

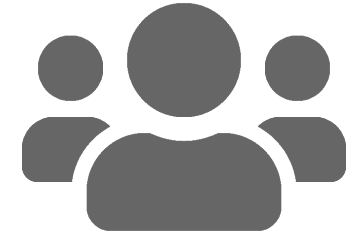
➤ Rholnc has something for their macros & GitHub

➤ Interoperable – Common metadata

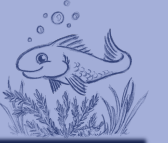
➤ PhUSE Scripts defined YAML

➤ Re-usable

➤ Ideally generic scripts & macros



Agenda



Introduction

Solutions

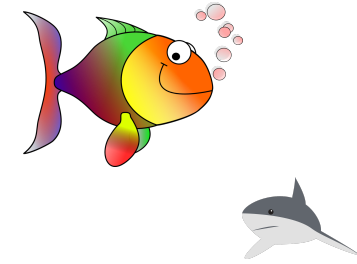
Challenges

Visions

Summary



Summary



- Many challenges but high opportunities
 - Don't overestimate motivation, financing is important
 - INVEST in open source
 - Be as open as possible
 - MIT for SAS scripts and macros
 - GNU for tools to avoid too strong commercializing
-

Summary



- Many tools & scripts already available
- Open Source Portal (www.glacon.eu/portal)

 Katja Glass Consulting

Home Overview Search Projects Blog Info

OPEN SOURCE PORTAL

For Clinical Study Evaluations

Why?

Currently it is very difficult to investigate which open source solutions are available for clinical study evaluations. There are quite some lists available for open source R programs. PhUSE has a R-Shiny App to display the PhUSE content. But still it is very tough to investigate what is available, especially when searching for a specific area.

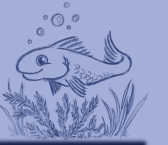
What?

This page will be a link collection of open source solutions, programs and scripts for clinical study evaluations. Additional metadata will be stored and a user friendly search mask as well as different navigations are made available.

How?

The content is collected manually. Further information and metadata are derived according available metadata and header analysis. If you want to provide additional input, please get in touch with me via info@glacon.eu. Additional content, views and also edit facilities will be added in the future.

Thanks!



Katja Glass Consulting

info@glacon.eu

www.glacon.eu

www.glacon.eu/portal