

Katja Glass  
Consulting

# Open Source for Pharma

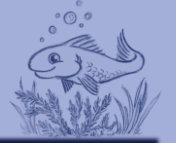
---

Solutions, Challenges  
and Visions



# Agenda

---



- Introduction
  - Solutions
  - Challenges
  - Visions
  - Summary
- 



# Introduction

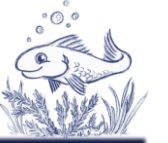
---



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

# Introduction

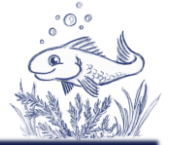
---



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

# Introduction

---



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

---



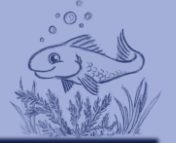
- Open Source FAIR for Scripts
  - Findable
  - Accessible
  - (Interoperable)
  - Re-usable

**SAS®**

---

# Agenda

---

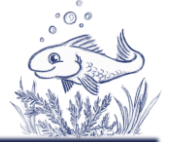


- Introduction
  - **Solutions**
  - Challenges
  - Visions
  - Summary
- 



# 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
  - ...

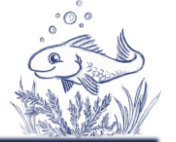


**Can R be used in  
Clinical Study Evaluations?**

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

---

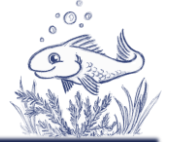
# Solutions



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



# Solutions



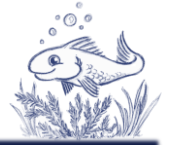
- Visual define.xml Editor (<http://defineeditor.com>)
  - Language: JavaScript / HTML
  - By Dmitry Kolosov & Sergei Krivtsov
  - Edit define.xml

A screenshot of the 'Visual Define-XML Editor' web application. The interface has a top navigation bar with tabs: DATASETS, VARIABLES, CODELISTS, CODED VALUES, DOCUMENTS, ARM SUMMARY, and ANALYSIS RESULTS. The main content area is titled 'Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)'. Below the title is an 'ADD ANALYSIS RESULT' button and a list icon. The configuration section includes:

- 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:** Includes icons for adding, linking, and opening in a new window.
- Datasets:** Includes a list icon and a 'Dataset' dropdown set to 'ADQSADAS'.
- Selection Criteria:** Includes an edit icon and the text: 'PARAMCD EQ 'ACTOT' AND AVISIT EQ 'Week 24' AND EFFFLEQ EQ 'Y' AND ANL01FL EQ 'Y''
- Analysis Variables:** Includes add and remove icons and the text: 'CHG (Change from Baseline)'

# Solutions

---



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



`%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)

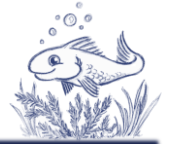
```
%mf_mkdir
```

```
%mf_getVarCount
```

```
%mp_dirlist
```

---

# Solutions



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

The screenshot shows the SASUnit web interface. The left sidebar displays a tree view of test scenarios, with 'saspgm/nobs\_test.sas' selected. The main content area shows the details for scenario 010, including a table of test cases. Below this, scenario 011 is also shown with its test case table.

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	✓

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

ADSL Codebook 150 of 150 (100.0%) rows selected.

Codebook Data Listing Charts

Controls Hide

Group by None

SITE	SITEID	SEX	RACE	ARM	ARMCD	SBJTSTAT	SAFFL	SAFFN	ANYAEFL	ANYCMFL
Site 01	02	F	Other/Mixed	Placebo	PLACEBO	Early Termination	Y	0	Y	Y
Site 02	03	M	Black	Treatment A	TRTA	Ongoing	N	1	N	N
Site 03	04		Hispanic	Treatment B	TRTB	Screen Failure				
Site 04	05		White	Screen Failure	SCRNFAIL	Completed				

Automatically generated data summaries for each column. Toggle Details: Show All Details Hide All Details

- ▶ 'USUBJID'
- ▶ 'SITE'
- ▶ 'SITEID'
- ▶ 'AGE'
- ▶ 'SEX'
- ▶ 'RACE'
- ▶ 'ARM'
- ▶ 'ARMCD'
- ▶ 'SBJTSTAT'
- ▶ 'RFSTDTC'
- ▶ 'RFENDTC'
- ▶ 'RFENDY'

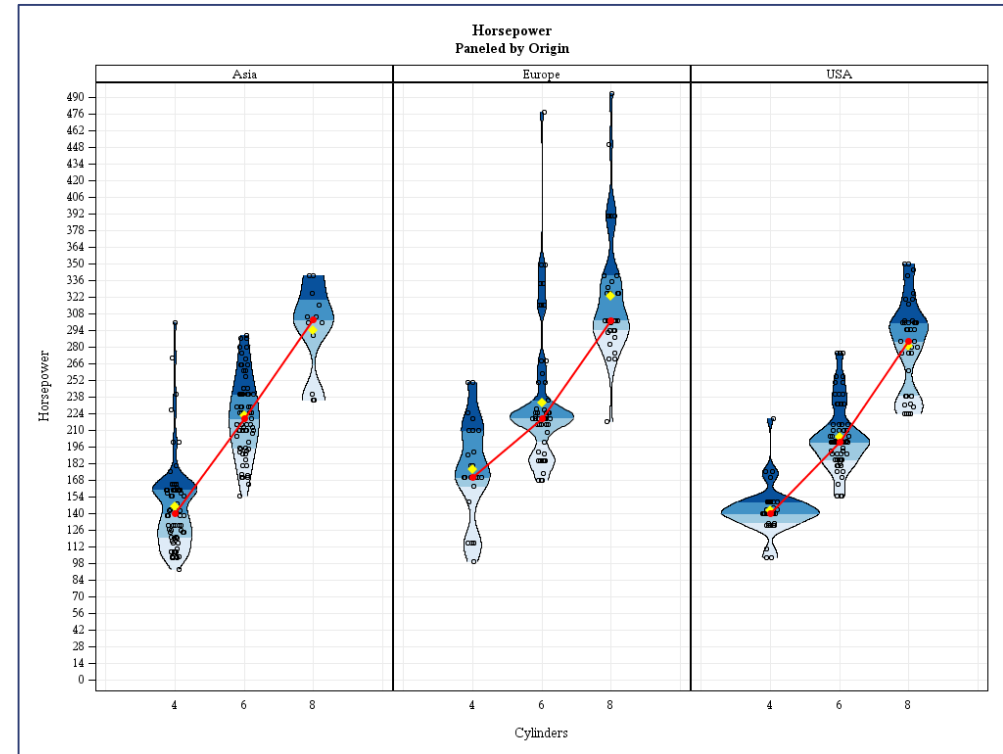
# Solutions



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

**SAS®**

**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

---

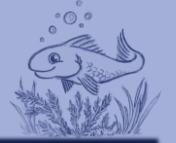


- Hidden Jewels
  - SAS™ Support Pages
  - Papers
  - Community Lists (SAS-L, Stackoverflow, ...)

**SAS®**



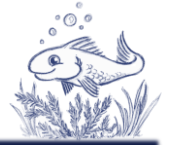
# Agenda



- Introduction
- Solutions
- **Challenges**
- Visions
- Summary



# Challenges



## User Perspective

Functionality

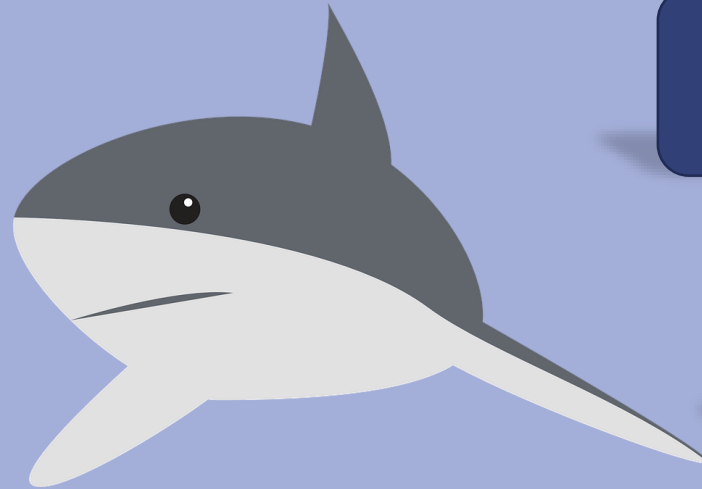
Validation

Documentation

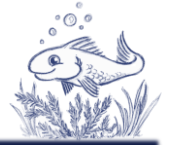
Support

Training

Maintenance

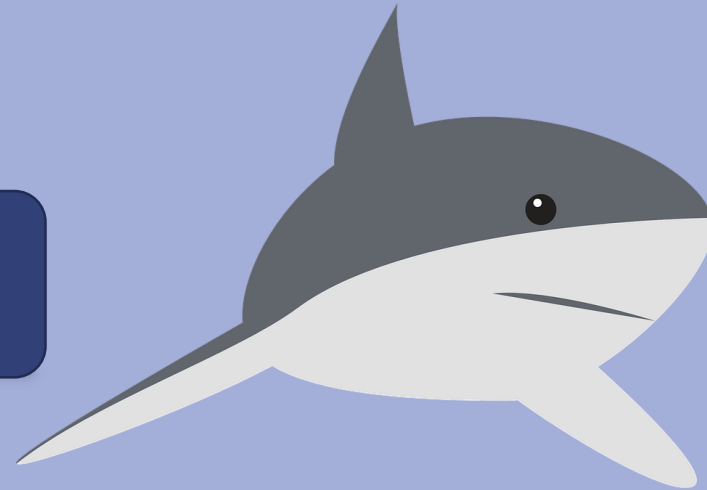


# Challenges



## Developer Perspective

Legal

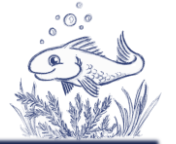


Time  
Management

Support  
Handling

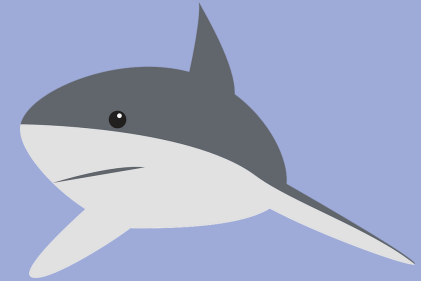
Financing

# Challenges



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

Documentation



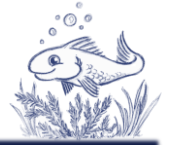
- Why do people do things?

Motivation

Goal

Money

# Challenges



## ➤ PhUSE Collaboration Projects

Motivation

Business Need

Functionality

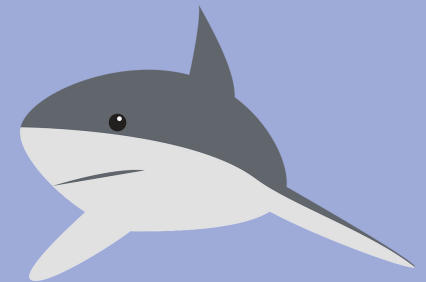
Maintenance

Documentation

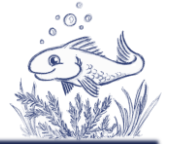
Support

Training

Validation



# Challenges



## ➤ Pinnacle21 Community Edition

Shifting  
over time



Motivation  
Make Money

Functionality

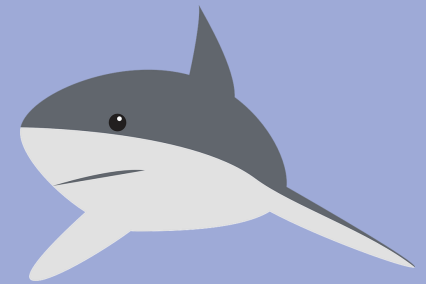
Maintenance

Documentation

Support

Training

Validation

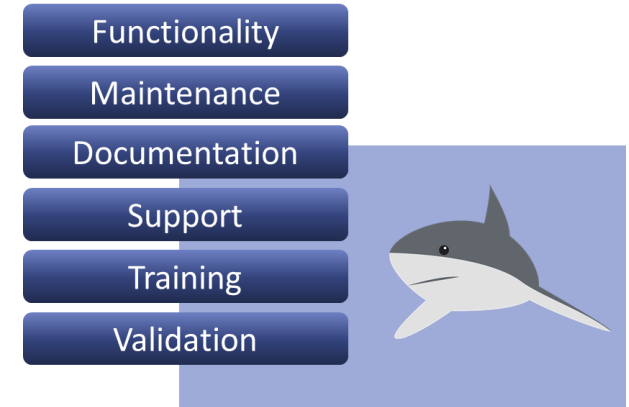


# Challenges

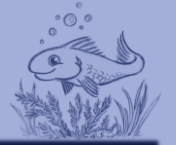


## ➤ RPact

- 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



# Agenda

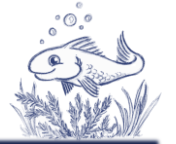


- Introduction
- Solutions
- Challenges
- **Visions**
- Summary



# 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

---



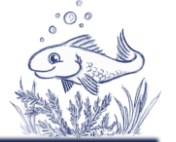
- Documentation is important!
  - Just do it
  - Try to motivate for documentation
  - Hire people for documenting



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

# Visions

---

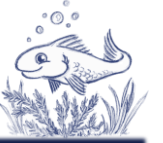


- New Open Source Finance Concepts
  - Support Open Source through
    - Donations
    - Sponsorship
    - Funding
  
  - Create “Pacts” to follow common goals, **OPEN**

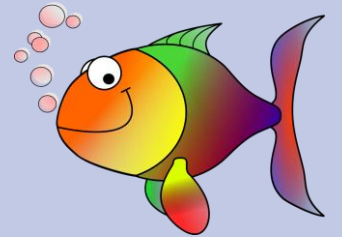
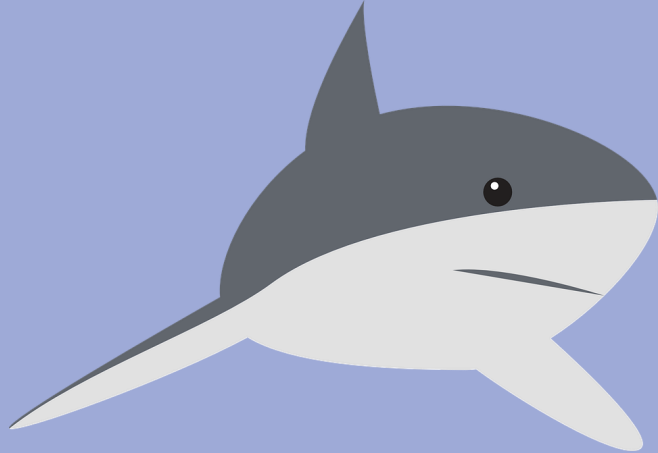


# Visions

---

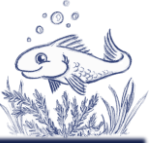


- Silicon Valley
  - 70 – 95% of startups fail
  - 5-30% becoming a success is enough



# Visions

---



## ➤ FAIR

➤ Findable - Open Source Portal

➤ [www.glacon.eu/portal](http://www.glacon.eu/portal)

➤ Accessible – CRAN like download platform

➤ Rholnc has something for their macros & GitHub

➤ Interoperable – Common metadata

➤ PhUSE Scripts defined YAML

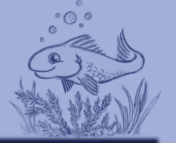
➤ Re-usable

➤ Ideally generic scripts & macros



# Agenda

---

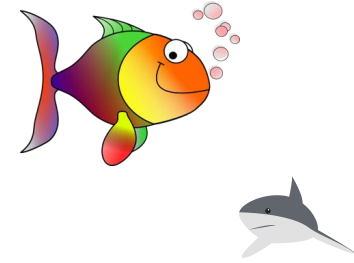
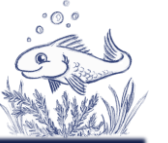


- Introduction
  - Solutions
  - Challenges
  - Visions
  - Summary
- 



# 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](http://www.glacon.eu/portal))

A screenshot of the 'Open Source Portal' website. The header is purple and contains the logo 'Katja Glass Consulting' on the left and navigation links 'Home', 'Overview', 'Search', 'Projects', 'Blog', and 'Info' on the right. The main content area has a blue background with white circles and the title 'OPEN SOURCE PORTAL' in large white letters, with the subtitle 'For Clinical Study Evaluations' below it. The content is organized into three columns: 'Why?', 'What?', and 'How?'.

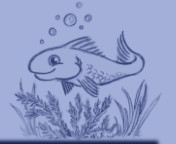
**Why?**  
Currently it is very difficult to investigate which open source solutions are available for clinical study evaluations. There are quite some lists available for open source R programs. PhUSE has a R-Shiny App to display the PhUSE content. But still it is very tough to investigate what is available, 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](mailto:info@glacon.eu). Additional content, views and also edit facilities will be added in the future.

# Thanks!

---



Katja Glass Consulting

[info@glacon.eu](mailto:info@glacon.eu)

[www.glacon.eu](http://www.glacon.eu)

[www.glacon.eu/portal](http://www.glacon.eu/portal)