

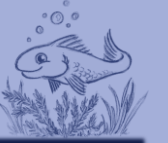
Katja Glass
Consulting

Clinical Data Science

Going the
Open Source Route



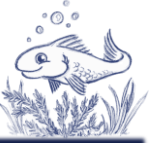
Agenda



- Introduction
 - Clinical Data Science
 - Collaborations
 - Available Open Source
 - Summary
-



Introduction

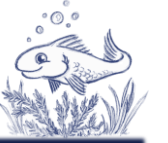


Clinical Data Science

- Classical Clinical Data Analysis
 - Defined methods
 - Traditional programming concepts
 - Highly regulated environment
- Clinical Data Science
 - Experimenting with methods & technologies
 - Alternative processes (Risk based approach)
 - Gaining additional insights



Introduction



Definition Open Source:

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:

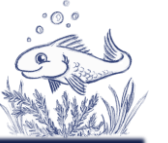
- Web Development (bootstrap, JQuery, ...)
- Developer IDEs (Eclipse, Atom, ...)
- Operating System (Unix, Android, ...)
- Tools, Applications, Source Code, Code Snippets



Need it for:

- Clinical Study Evaluations & Related Tasks
-

Introduction

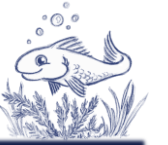


Typical providers:

- Often single-person projects with high motivation (free time)
- Result of working groups, papers (!!! include license !!!)
- Companies/People to show know how
- Companies with business model (few)



Introduction



Content:

- Typically no financing, personal motivation counts



Functionality

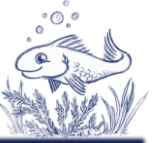
Documentation &
Communication

Motivation Line

Training

Validation

Introduction

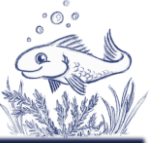


High Motivation -> Many Open Source Solutions

- COVID-19
 - Free datasets (Johns Hopkins Center, ...)
 - CDISC publish COVID 19-Standards
 - > 32.000 GitHub Projects related to COVID-19
 - Kaggle Challenges
 - Analysis & Visualization sources



Introduction



Validation:

Copy program from another study:

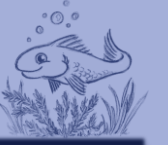
- Who is responsible for this program in this study?
- How is validation be performed?

Copy/Use open source program:

- Same rules apply
 - Study programmer is responsible
 - Validation has to be performed



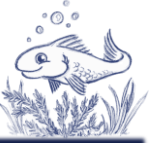
Agenda



- Introduction
 - **Clinical Data Science**
 - Collaborations
 - Available Open Source
 - Summary
-

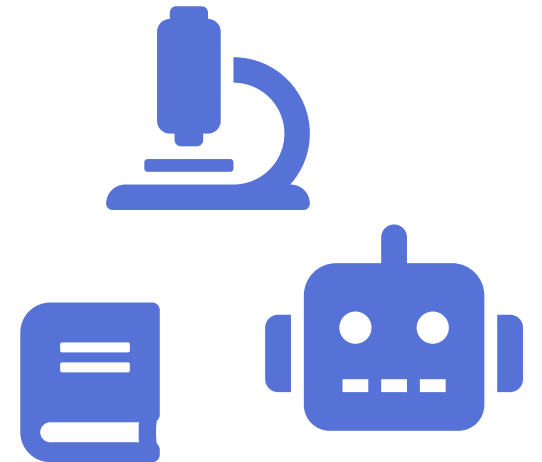


Clinical Data Science

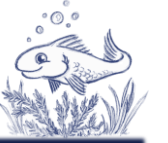


Clinical Data Science – new focus on:

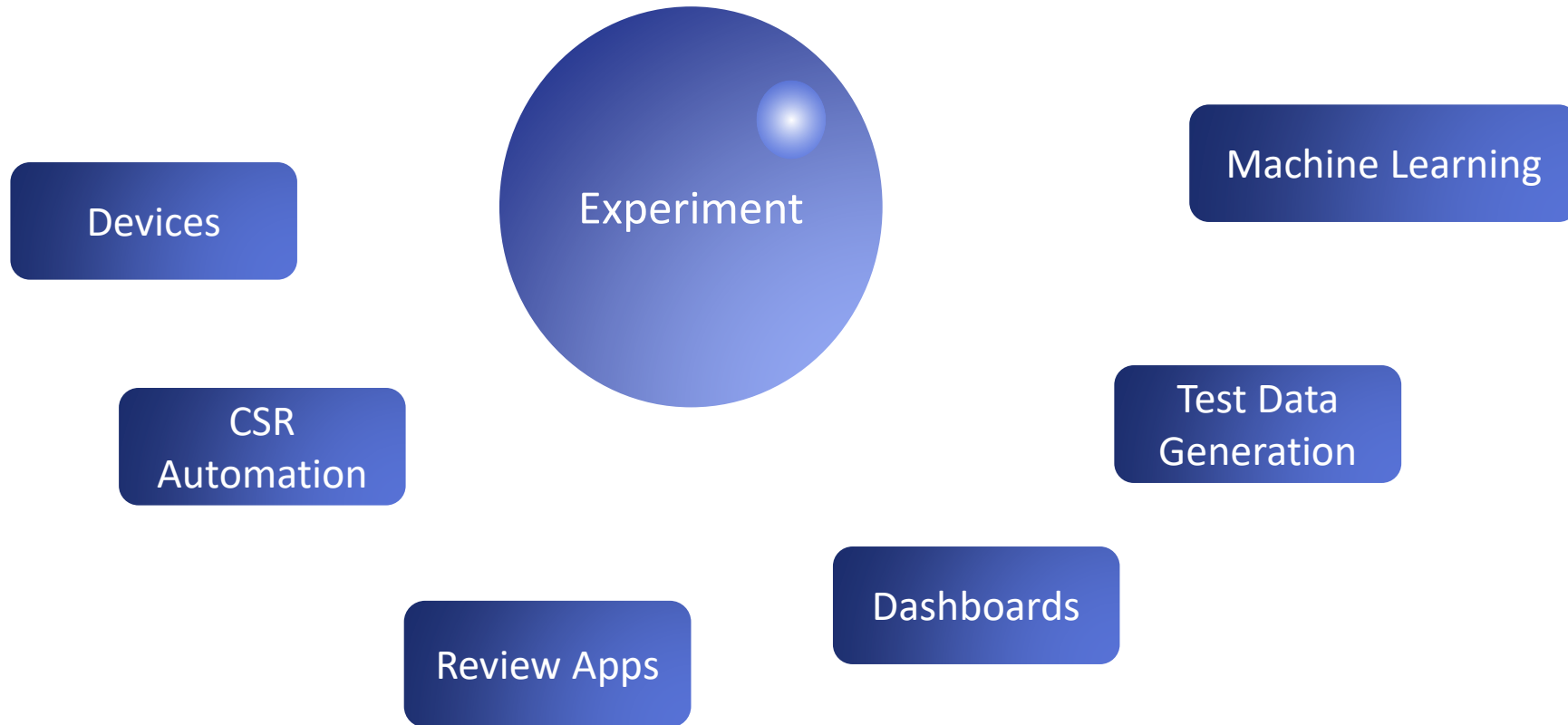
- Adapt new technologies
- Apply new devices
- Experimentation and Elaboration
- Learning new programming languages
- New ways to perform clinical evaluations
- New processes and automatisms



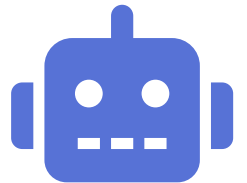
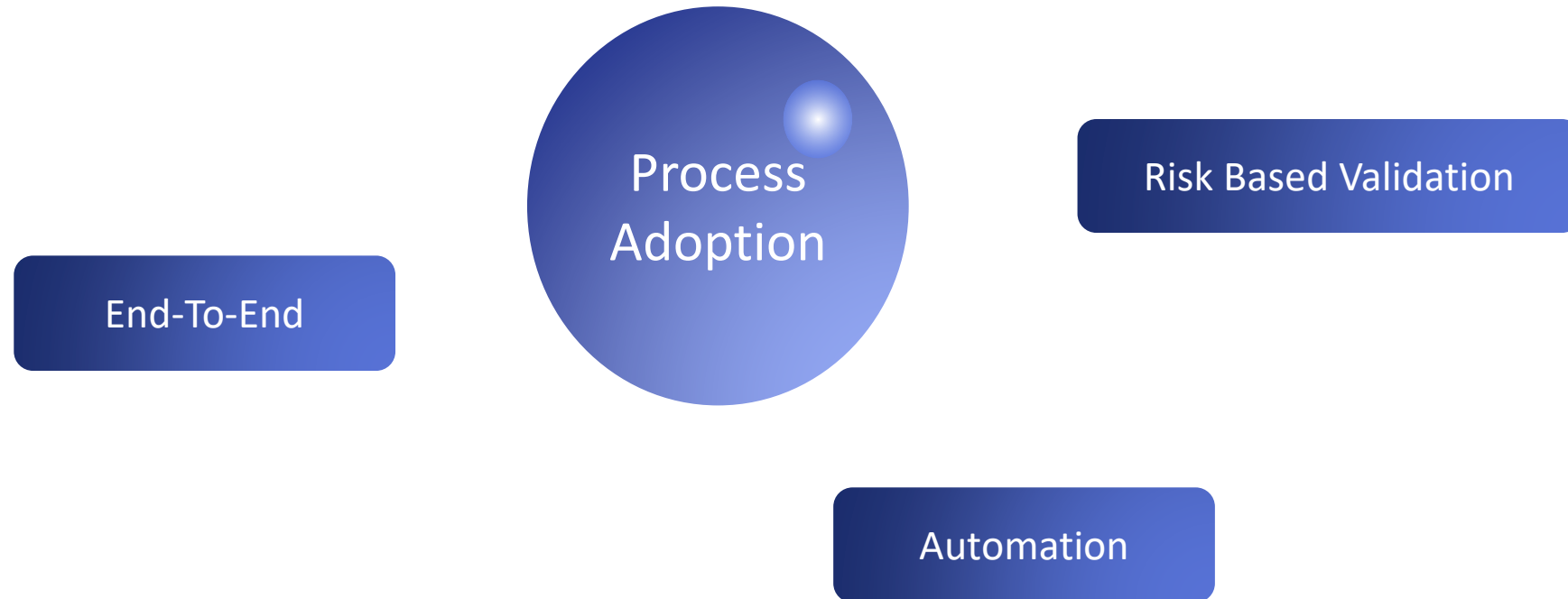
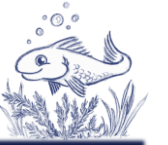
Clinical Data Science



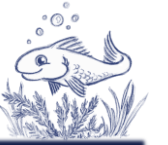
Clinical Data Science



Clinical Data Science



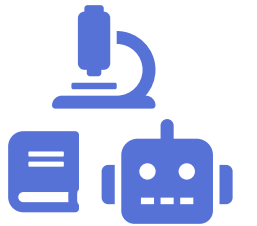
Clinical Data Science



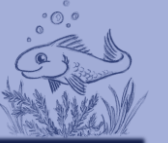
➤ Going the Clinical Data Science Route alone?



- Inefficient
- Expensive



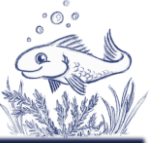
Agenda



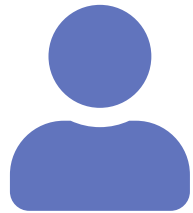
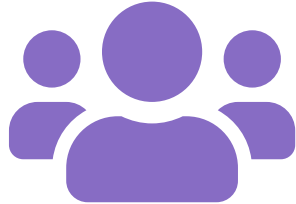
- Introduction
 - Clinical Data Science
 - **Collaborations**
 - Available Open Source
 - Summary
-



Collaborations



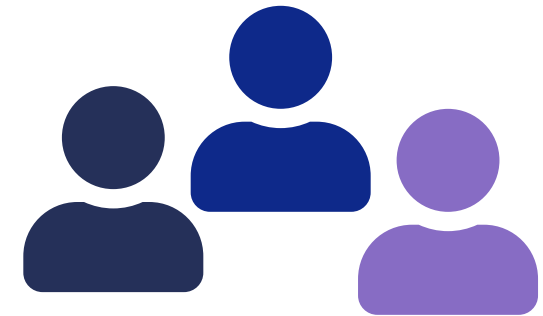
Individuals in
Companies



Educations:
Papers,
Webinars,
Online Courses,
Books

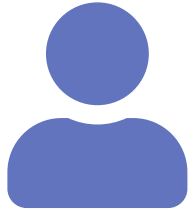
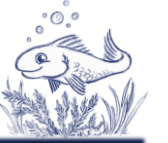


Conferences:
Education &
Discussion



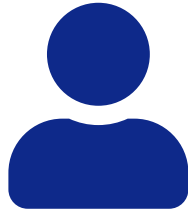
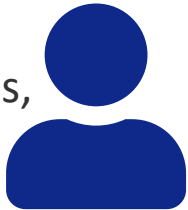
Working Groups:
Discussions &
Collaborations

Collaborations

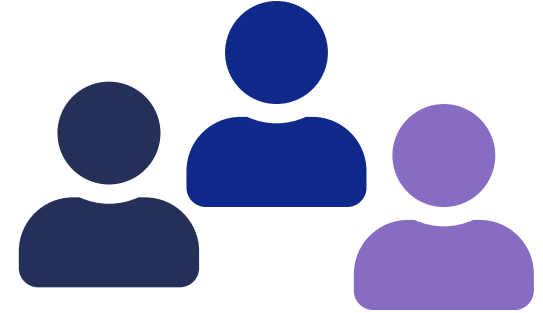
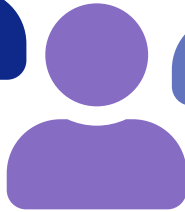


Educations:

Papers,
Webinars,
Online Courses,
Books



Conferences: Education & Discussion

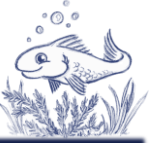


Working Groups:

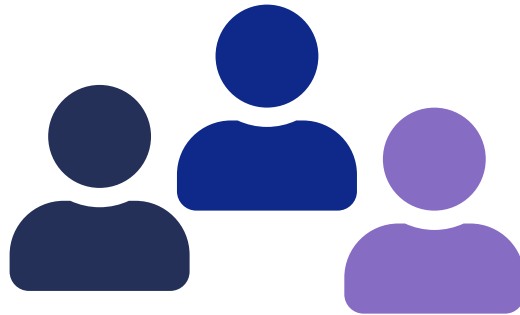
Discussions &
Collaborations

➤ **Get more out of these!**

Collaborations



- Use Open Source!
- Ultimate Collaboration!

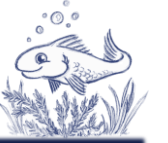


**Discussions &
Collaborations:**
Working Groups



**Implementation &
Discussions:**
Open Source Projects

Collaborations – Open Source



Advantages

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



Collaborations – Open Source

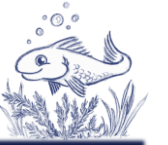


Challenges

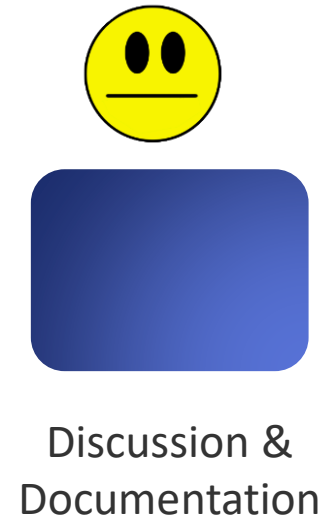
- Communication
- Documentation
- Training
- Validation
- Financing
- ...



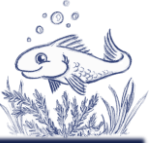
Collaborations – Open Source



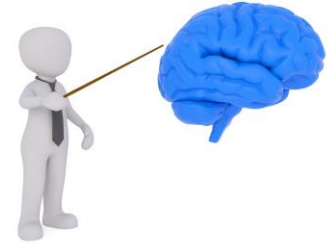
Creation Effort



Collaborations – Open Source

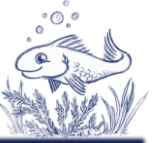


- Consider Motivation
 - Personal
 - Show talent, gain customers
 - Commercial background



High quality & validation likely only
when commercially motivated

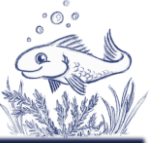
Collaborations – Open Source



- Where would the CDISC standards be without financing?
- Where are the PhUSE working groups without financing?
- What could the working group status be with financing?



Collaborations – Open Source



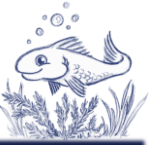
Basis is available!

- PhUSE Education
 - Homepage under restructure construction
 - [Link List](#) from Open Source Project
- PhUSE Conferences & Webinars
- PhUSE Working Groups
 - Partly creating “Open Source”



More progress
with financing

Collaborations – Open Source

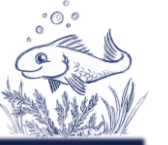


Why Clinical Data Science?

- Companies just Starting this route
- “Start from Scratch”
- Less available & adopted solutions
- Learn, experiment & process adoption

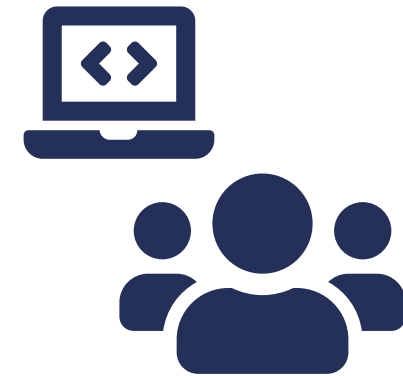
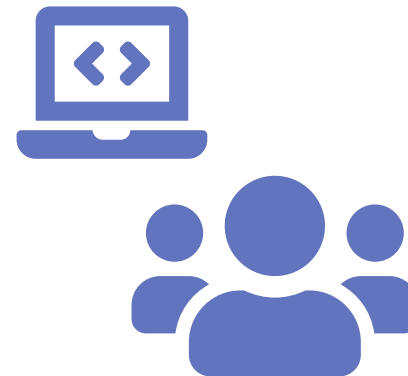


Collaborations – Open Source

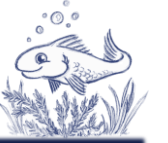


Narratives Use Case

- Different companies implementing narratives automation
- Similar processes, similar technologies
- Different implementations



Collaborations – Open Source



Clinical Science Cases

- Why not starting all together that route?
- Why not open source?
- Create “Gold” standard



Collaborations – Open Source



Process, Quality, Validation

- Think about financing concepts

Possible Ways

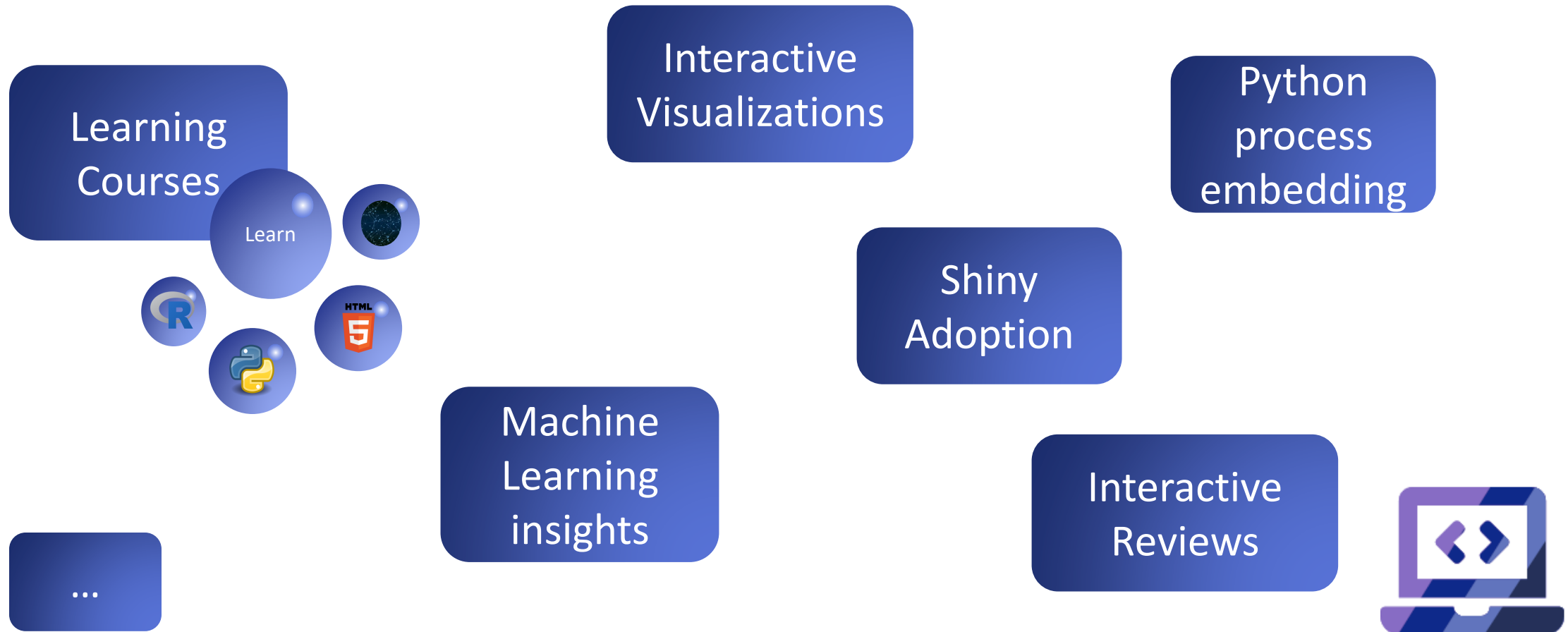
- “Small” open source packages
- “Brick” them together
- Ask students, contractors, companies



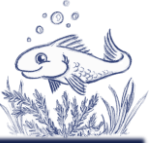
Collaborations – Open Source



Possible Use Cases



Collaborations – Use Case



Interactive Reviews - Example Use Cases:

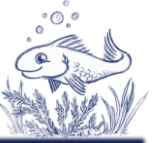
- App to interactively review study
- Authorities prefer standard, not single solutions

How to start?

- Lonely road
- Collaborative - non-commercial
- Collaborative - commercial



Collaborations – Use Case



Standalone

- Project setup
- Discussions, Decisions, Implementations
- Validation, Training, Documentation



Collaborative - non-commercial

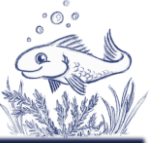
- Working Group & do it yourself



Collaborative – commercial

- Working Group & support by vendor
-

Collaborations – Use Case



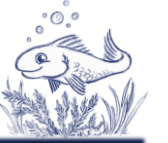
Collaborative (Example)

- Define background, processes
 - Provide test data, rough functionality
 - Technology to checkout (e.g. RShiny, Python, Web)
 - Define license (MIT, GNU)
- Experimenting
 - Multiple pilots by employees, students, externals
 - Other available open source solutions
 - Like “PhUSE Innovation Challenge”

Manage
&
Document



Collaborations – Use Case



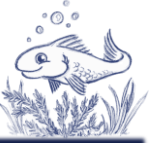
Collaborative (Example)

- Route definition
 - One Pilot to the next step
 - Discussions
 - In-house-data tests
 - Finetuning
- Finalization
 - Documentations, Trainings, Communications
 - Tests, Validations

Manage
&
Document



Collaborations – Use Case

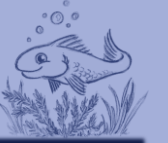


Recommendations

- Management and documentation MOST important
- Transparency
- Process likely faster when parts are “paid”
- Input from communities, students etc.



Agenda



- Introduction
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 - Collaborations
 - **Available Open Source**
 - Summary
-



Available Open Source Solutions



Collaboration Open Source Projects

- PhUSE Scripts
- SEND Data Factory
- RPact (Commercial Collaboration)
- FDA Jumpstart Scripts

Open Source Projects:

- SASUnit
- SAS Macros by single persons
- Visual Define.xml Editor



Available Open Source Solutions



www.glacon.eu/portal (google: clinical open source portal)


The screenshot shows a web browser displaying the 'OPEN SOURCE PORTAL' website. The browser's address bar shows 'www.glacon.eu/portal/#/'. The website has a purple header with the 'Katja Glass Consulting' logo and navigation links: 'Home', 'Overview', 'Programs', 'Projects', and 'Info'. The main content area has a blue background with white circles and the text 'OPEN SOURCE PORTAL' and 'For Clinical Study Evaluations'. Below this, there are three columns: 'Why?', 'What?', and 'How?'. The 'Why?' column explains the difficulty of finding open source solutions for clinical study evaluations. The 'What?' column describes the portal as a link collection of open source solutions, programs, and scripts, with additional metadata and a user-friendly search mask. The 'How?' column states that the content is collected manually and that further information and metadata are derived from available metadata and header analysis. It also provides contact information: 'info@glacon.eu'.

Why?	What?	How?
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	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	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 .

Available Open Source Solutions




➤ Overview -> Available Tools (www.glacon.eu/portal)

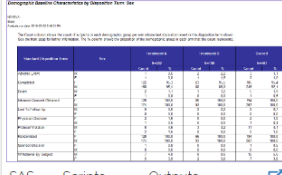
**Katja Glass Consulting**

Home Overview Programs Projects Info


Visual Table

FDA Jumpstart Scripts

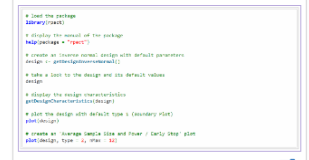
Clinical study evaluations scripts used by the FDA in their JumpStart tool has been developed based on SDTM standard. The FDA contributed the JumpStart SAS scripts so these are available on the PhUSE repository for use.




SAS Scripts Outputs

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.



R Tool Statistics

Pinnacle21 Community Edition

This tool supports various CDISC processes including the validation and creation of the

**Katja Glass Consulting**

Home Overview Programs Projects Info






Visual Table

Name	Description	Type	Language	Last Updat..	License	Author Type	Area (Users)	Area (Works..	Size
		Show All ▾	SAS ▾			Show All ▾	Show All ▾	Show All ▾	Show All ▾
FDA Jumpstar	Clinical stud..	Scripts	SAS	2016-03-11	MIT	individual	ANALYST	Outputs	medium
SASUnit	SASUnit is a..	Tool	SAS	2019-07-08	GPLv3	company	DM, ANALY..	Programmi..	medium
Spectre (Rolar	A complete ..	Scripts	SAS	2015-06-17	Unlicense	individual	ANALYST	Outputs	large
SAS Macros b	Scott Bass ..	Scripts	SAS	2019-10-16	Unlicense	individual	DM, ANALY..	Programmi..	medium
SAS Macros b	Much qualit..	Scripts	SAS	2019-11-25	MIT	company	DM, ANALY..	Programmi..	medium
PhUSE White	PhUSE has ..	Scripts	R, SAS	2019-02-25	MIT	individual	ANALYST	Outputs	medium
Rholnc Plots	Multiple Plo..	Scripts	SAS	2019-08-08	MIT	company	ANALYST	Visualization	small
Going Translat	In this proje..	Scripts	R, RDF, SAS	2019-08-01	MIT	individual	PROG	Programmi..	small
PhUSE White	24 utility ma..	Scripts	SAS	2017-03-21	MIT	individual	PROG	Programmi..	small
PhUSE Contril	There are v..	Scripts	R, SAS, Other	2019-07-20	MIT	individual			small

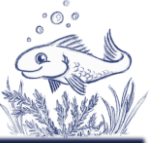
Available Open Source Solutions



- Programs -> search programs & macros (www.glacon.eu/portal)

 Katja Glass Consulting							
Home Overview Programs Projects Info							
Tool	Name	Description	Type	Class	Lang_	Mod Date	Linen...
Show All 			Show 	Show 	SI 		
<div>Show All</div> <div>FDA Jumpstart Scripts</div> <div>Macro People Core - SAS Macros</div> <div>Roland's SAS® Macros</div> <div>SAS Macros by Scott Bass</div> <div>Whitepaper Scripts</div>		MedDRA at a Glance Analysis Panel - The	Script	Tool	SAS	2011-05-08	653
		MedDRA at a Glance Analysis Panel shows the					
		user the adverse events that occurred in the					
		study according to their place in the MedDRA					
		hierarchy and allows them to compare any two					
		arms according to a number of statistics.					
FDA Jumpstart S	ae_oncology_v1	AE Toxicity Analysis Panel - The AE Toxicity	Script	Tool	SAS	2011-06-02	408
		Analysis Panel provides the user with different					
		analyses to help understand the adverse events					
		present in the study and the frequency of their					
		occurrence by treatment arm. Statistical and					

Available Open Source Solutions

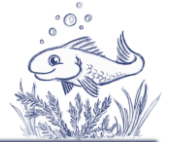


Commercial Open Source?

- Pinnacle21 Community
 - Protective license
 - Current version not completely open source
- RPact
 - Package free for all, LGPL-3 license
 - Additional services, validation documentation etc. for members
- Corona Warn-App (Germany)
 - Paid by country, created by companies, made open source
- Reindeer (Render SAS Results into Word)
 - Sponsored Open Source




Available Open Source Solutions




➤ Reindeer (Render SAS Results into Word)

- Open Source (MIT License)
 - Sponsored by ClinStat GmbH
 - Intuitive & Easy to use
 - Include Documentation
 - Embed Figures, RTF & Listing into Word
-
- Small scale project
 - Free for all
 - Paid by one
 - No validation

 Katja Glass
Consulting
(Developer)

Reindeer

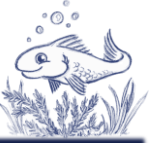
 ClinStat
www.clinstat.eu
(Sponsor)

**Reindeer –
a Result Render Tool**

Run

Configuration**General**

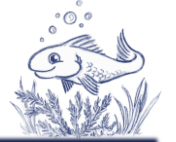
Available Open Source Solutions



- Enable more open source
 - Allow employees & contractors to publish open source
 - Join open collaborations
 - Invest in open source
 - Apply license to papers, blogs



Available Open Source Solutions

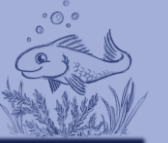


- More Informationen
 - Katja Glass Consulting @YouTube
 - Open Source Portal (www.glacon.eu/portal)
 - Open Source Guides (<https://opensource.guide/>)

The screenshot shows the YouTube channel page for 'Katja Glass Consulting'. The navigation bar at the top includes 'ÜBERSICHT' (selected), 'VIDEOS', 'PLAYLISTS', 'KANÄLE', 'DISKUSSION', and 'KANALINFO', along with a search icon. Below the navigation bar, the 'Uploads' section is active, displaying 'ALLE WIEDERGEHEN'. A grid of four video thumbnails is shown, each with a title, duration, and view count.

Video Title	Duration	Views	Time Ago
Using an Open Source SAS Macro - How to do?	33:29	41 Aufrufe	vor 2 Monaten
Open Source Portal for Clinical Study Evaluations - ...	4:37	49 Aufrufe	vor 4 Monaten
Open Source for Pharma - Solutions, Challenges and...	17:09	85 Aufrufe	vor 6 Monaten
Open Source Collaborations in Clinical Study Evaluations	6:42	16 Aufrufe	vor 7 Monaten

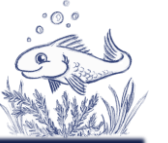
Agenda



- Introduction
 - Clinical Data Science
 - Collaborations
 - Available Open Source
 - **Summary**
-



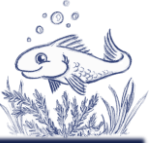
Summary



- Apply Open Source Solutions
- Support & Create Open Source
- Clinical Data Science ideal start point
 - Learn
 - Experiment
 - Process Adoption



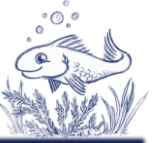
Summary



- Opportunities are high
- PhUSE supporting collaboration
- Going the next step with financed open source
 - Faster progress
 - More documentation
 - Less individual research



Summary

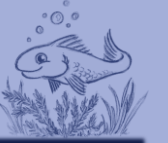


Don't go that route alone!



You might miss the easy way!

Thanks



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