



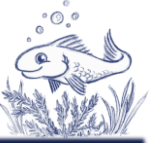
Katja Glass
Consulting

Open Source in Pharma

What's going on?



Disclaimer



The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the position of any mentioned organization or company.

Sources




- Conference presentations
- Social media (LinkedIn)
- Individual links
- Individuals



www.linkedin.com

www.lexjansen.com

SAS Conference Proceedings (1976 – present) ... and more

This searches **35228** conference papers from SAS Global Forum, SUGI, PharmaSUG, PhUSE, NESUG, SESUG, WUSS, MWSUG, PNWSUG, SCSUG, SEUGI, ... 

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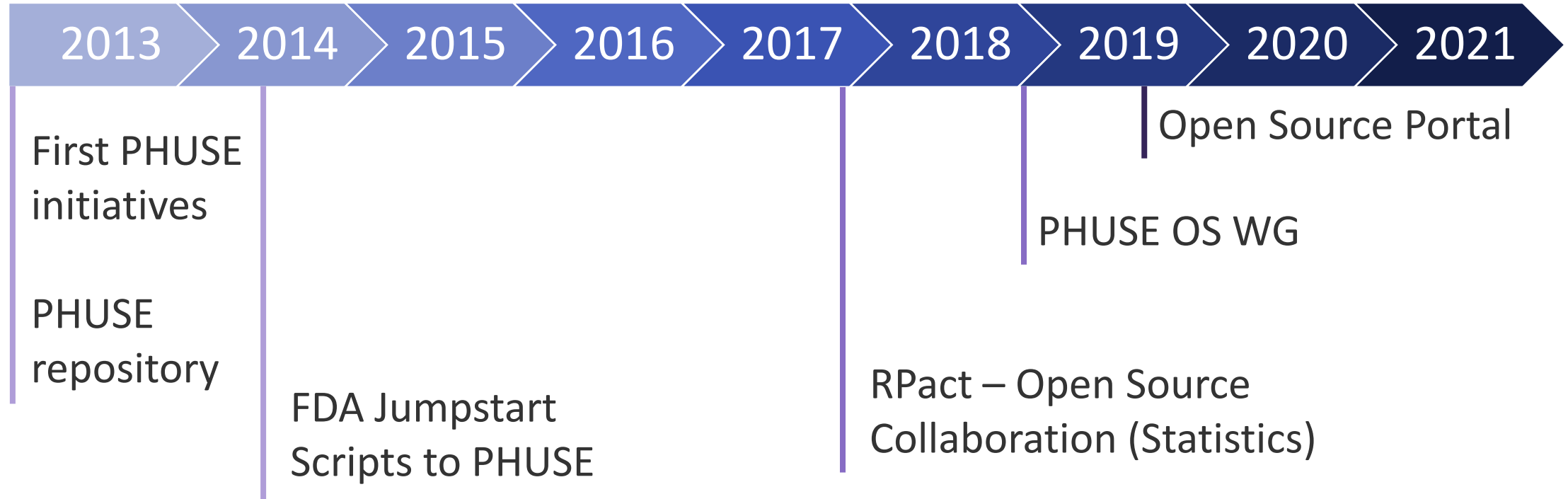
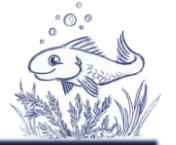


Perform a [search](#) for SAS papers based on title, author or keywords.

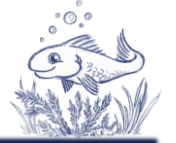
[Papers](#) written by [Lex Jansen](#).

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History



History



2013

2014

2015

2016

2017

2018

2019

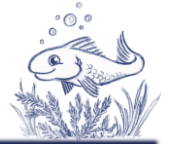
2020

2021

- Knowledge exchange (conferences)
- Working group success
- Collaboration
- R Discussions

Changes
need time

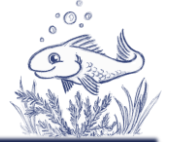
History



Open Source
in Pharma

BOOOOOOOM!

Organizations



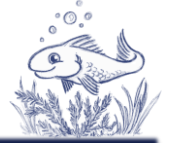
➤ PHUSE

- Working Groups, special open-source focus area
- General white paper
- R Initiatives

▼ **Data Visualisation & Open Source Technology**

- Best Practices for Interactive Analysis for Decision Making Submissions
- Clinical Statistical Reporting in a Multilingual World
- Julia Initiative for High Performance Computing
- R Environment System Qualification
- R Package Validation Framework
- R Shiny Interactive Forest Plot
- Test Dataset Factory

Organizations



➤ CDISC

➤ CDISC 360°

discussions, collaborations

➤ COSA

CDISC Open Source Alliance

➤ CORE

open-source project



Organizations – CDISC COSA



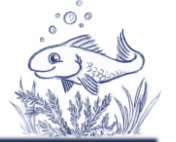
[...] supports, promotes, and sometimes sponsors open-source software projects [...]

- Repository (Information Hub)
 - Webinar done (18.11.2021)
 - Hackathons, discussion, guidance

 - Recently founded, potential high
-



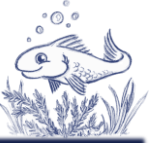
Organizations – CDISC CORE



- CDISC Conformance Rules
 - Open-source project, added to COSA
 - About executable conformance rules
 - Industry and Microsoft participations
- Many lessons learned
- Expecting open-source guidance



Universe of R



- Core driver
 - GSK
 - Roche
 - Atorus (2020)
 - Core business concept R open source packages



Universe of R



➤ R Consortium

- Setup Pharma area
- Pharma Members:
 - Biogen, Roche, GSK, Janssen, Merck
- R in Pharma (conference)

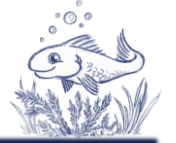


➤ Working groups

- RValidationHub (riskmetrics, white paper)
- The R adoption series
- R Tables for Regulatory Submission (RTRS)
- Submissions (to make “all R” regulatory submissions)



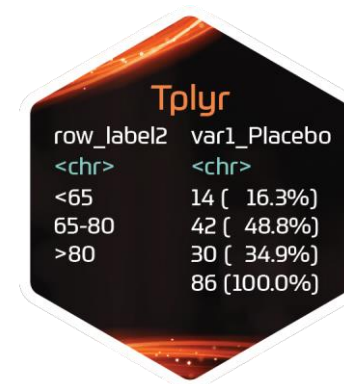
Universe of R



➤ Packages

- RTables (Roche since 2017) output
- pharmaRTF (Atorus) output
- Tplyr (Atorus) summaries
- admiral (Roche-GSK, planned OS) SDTM -> ADAM

- More already in planning phase
- End2End processes in R



Universe of R



➤ Processes

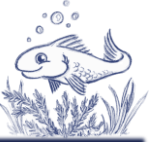
- thevalidatoR (R Package Validation Report)



➤ R in Pharma presentations:

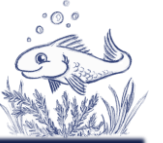
- R Package Validation at Roche
 - R Package Validation at Merck
“Statistical Analysis and Pathway to a Risk-based Assessment ...”
 - R Harmonization at Pfizer
“There’s only one R in Pfizer. Attempts to harmonise R ...”
 - End to End Toolkit (GSK, Atorus)
“Closing the Gap: Creating an End to End R Package Toolkit ...”
-

Started / Upcoming projects



- Novo Nordisk
 - Planning open source release of linked data tool in COSA (connected to CDISC 360° and TransCelerate DDF)
 - TLF Designer
 - New open source project started as COSA project
 - Looking for participants & content details
 - TransCelerate (Digital Data Flow)
 - Investigate in open source options
 - more to come
-

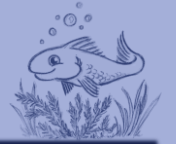
Summary



- Took time for open-source
- Huge initiatives ongoing / just started
 - CDISC: COSA, CORE
 - Pharma-collaboration: Roche-GSK
 - More not yet available
- Invest & participate



Questions?



Katja Glass Consulting

info@glacon.eu

www.glacon.eu

www.glacon.eu/portal
