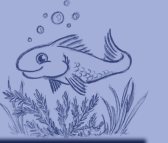


Single Day Event

Katja Glaß, Katja Glass Consulting
Part One

Proprietary vs. Open-Source – What's more FAIR?

Agenda



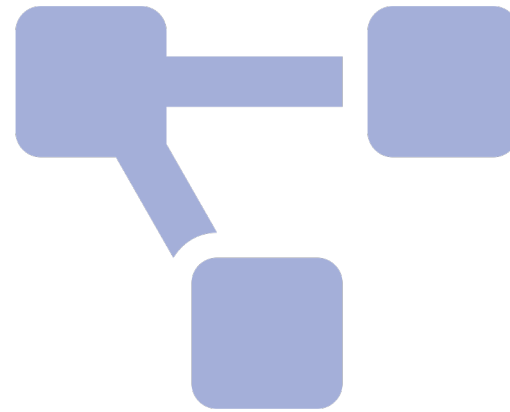
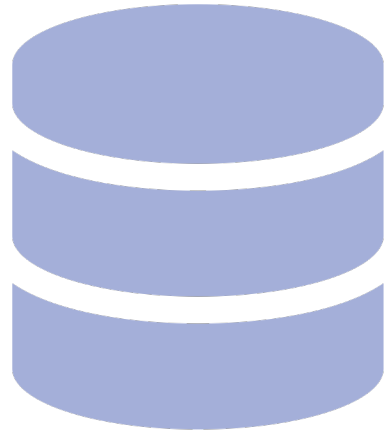
- Introduction
 - FAIR views
 - Money, Money, Money
 - Fairness & More
-



Introduction



➤ Associations with FAIR



➤ Developed for Data, applicable for much more

FAIR Views



- Proprietary Software (Sell-Software) vs. Open Source

F - Findable



FAIR Views



- Proprietary Software (Sell-Software) vs. Open Source
- Findable is an issue for all
 - What solutions exist (pay or open)?
 - No repository / knowledge graph with information
 - Open-Source has a portal (www.glacon.eu/portal)
 - Rely on conferences, social media, newsletters, word of mouth
- Need information hub(s)
 - Generic concept presented 2020-09,
 - Needs to be done & maintained



FAIR Views



➤ Proprietary Software (Sell-Software) vs. Open Source

A - Accessible

Proprietary



Information,
Presentations,
Demo

Open Source



Source fully,
Tools sometimes

FAIR Views



- Proprietary Software (Sell-Software) vs. Open Source

I - Interoperable

Proprietary



Specific
Integrations,
APIs (if available)

Open Source



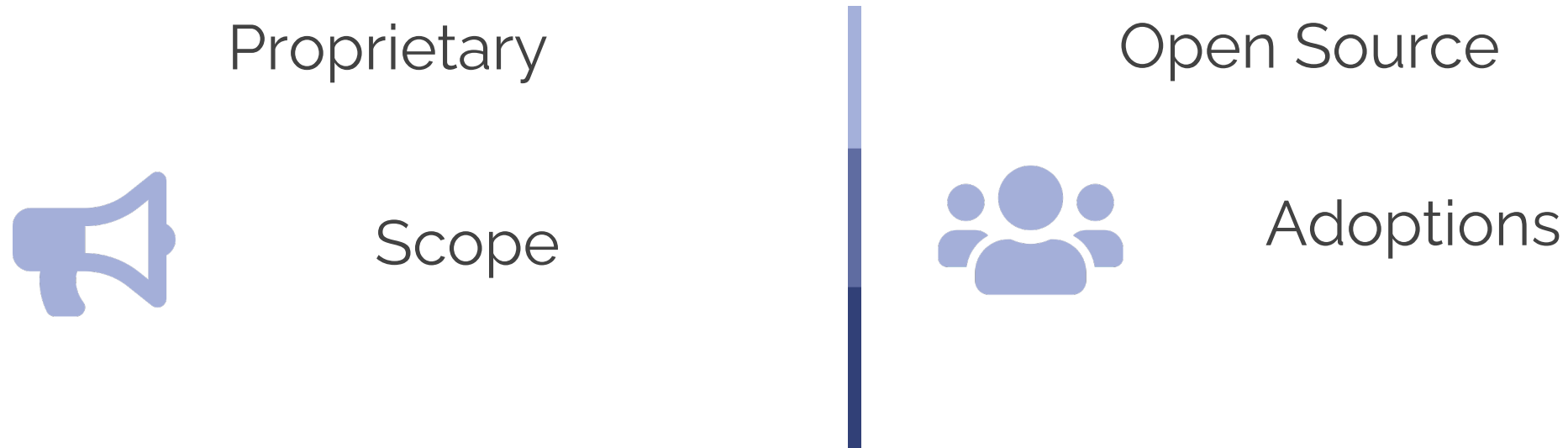
Often generic,
APIs

FAIR Views



- Proprietary Software (Sell-Software) vs. Open Source

R - Re-Usable



Money, Money, Money



- Reliability & Stability
- Maintenance & Service Level Agreements (SLA)
- **Cost**



Money, Money, Money



➤ Examples

Proprietary

- SAS
- P21 Enterprise
- MDR Tools

Open Source

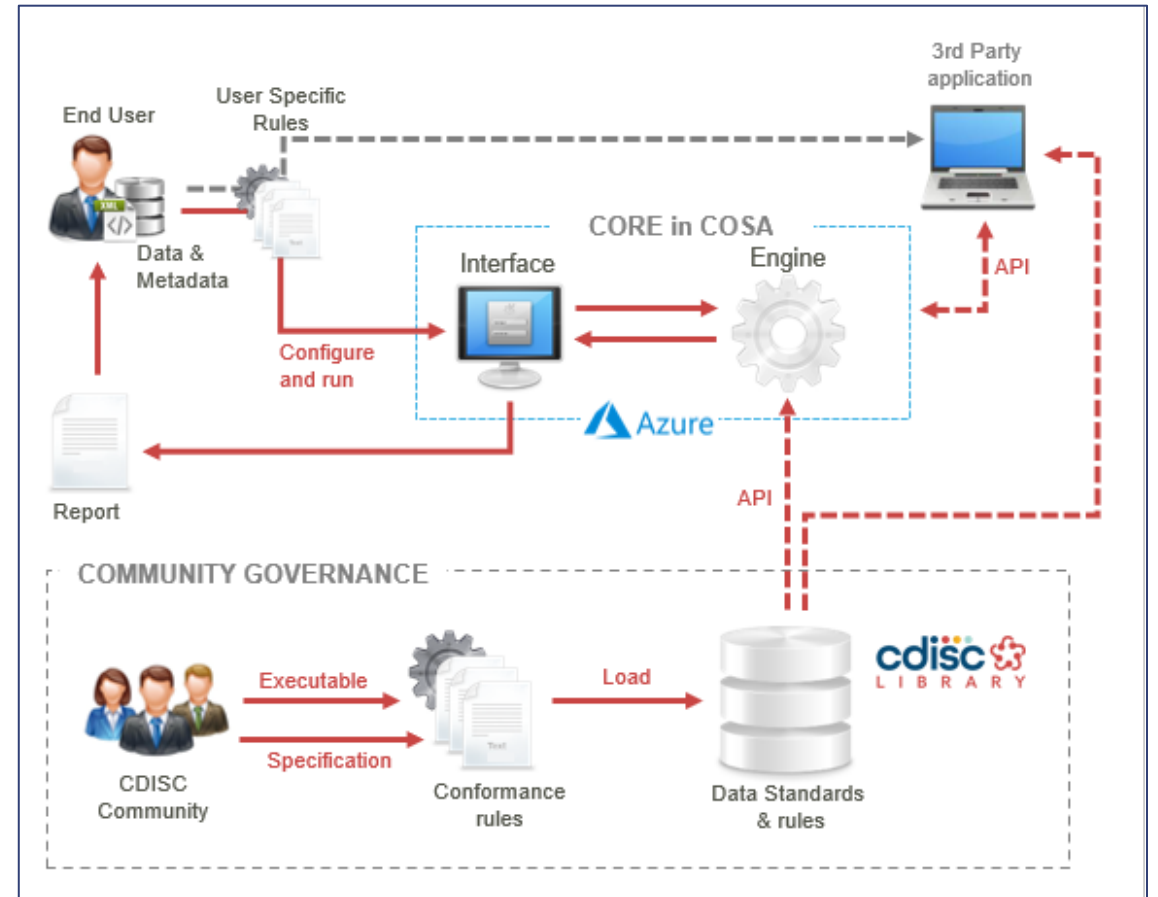
- R
 - CORE
 - admiral
-

Money, Money, Money



➤ Example **CORE**

- Huge CDISC project for executable conformance rules
- Will become part of COSA (CDISC Open Source Alliance)
- Minimal Viable Product Q2 2022



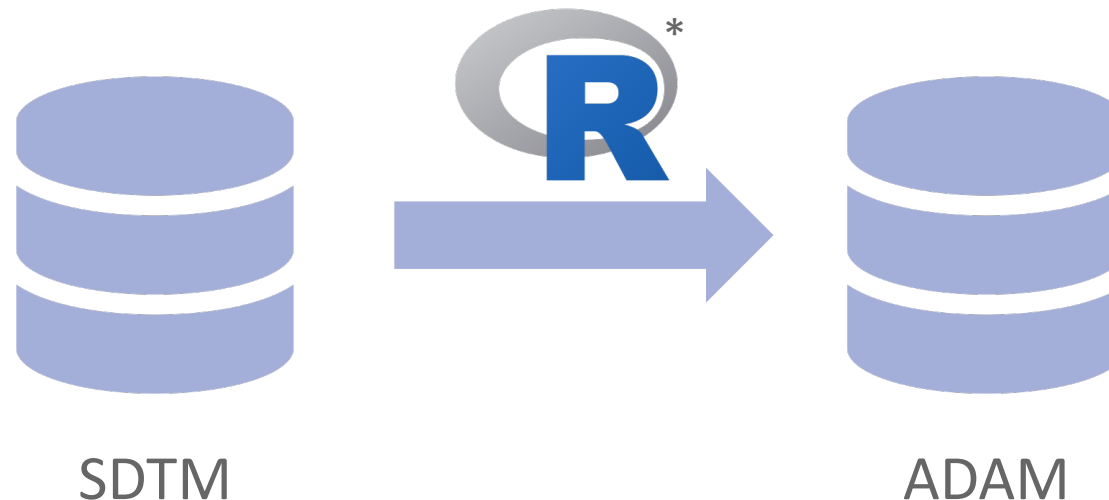
<https://www.cdisc.org/core>

Money, Money, Money



<https://roche-gsk.github.io/admiral>

- Example “**admiral**”
 - Roche-GSK collaboration
 - ADAM in R Asset Library
 - Planned as Open Source



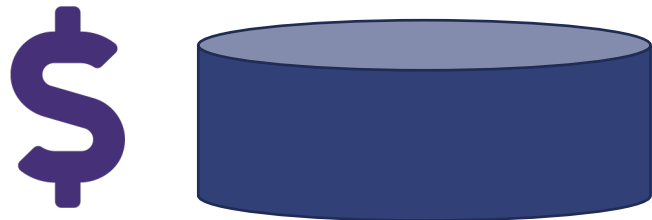
Money, Money, Money



➤ Development costs

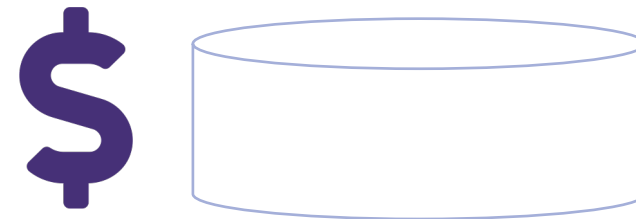
Proprietary

- One time
- Per year/month/item



Open Source

- None
- Own/contracted developer



Money, Money, Money

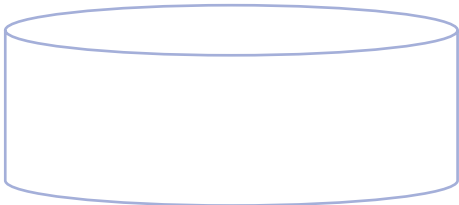


➤ Validation costs



Proprietary

- Included in price
- No transparency



Open Source

- Maybe available, require execution
- Own/contracted validation



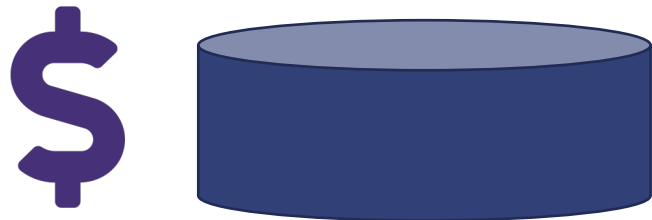
Money, Money, Money



➤ Environment setup

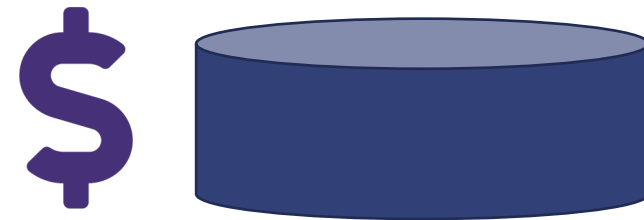
Proprietary

- Own resources / possible to buy-support



Open Source

- Own resources & knowledge



Money, Money, Money



- Environment setup - SAS vs. R
 - How many SAS experts needed to setup / maintain Server(s)?
 - How many R experts needed to setup / maintain Server(s)?

Expert
availability

Expert
costs



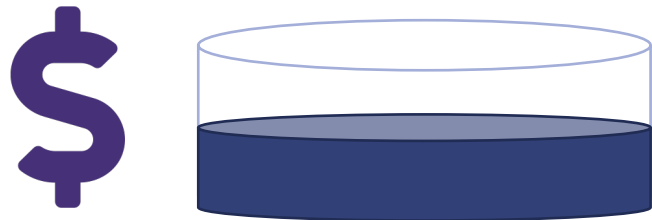
Money, Money, Money



➤ Maintenance costs

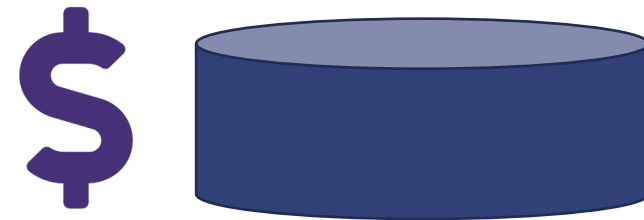
Proprietary

- Maybe included
- Extra SLA costs



Open Source

- Own/contracted developer



Money, Money, Money

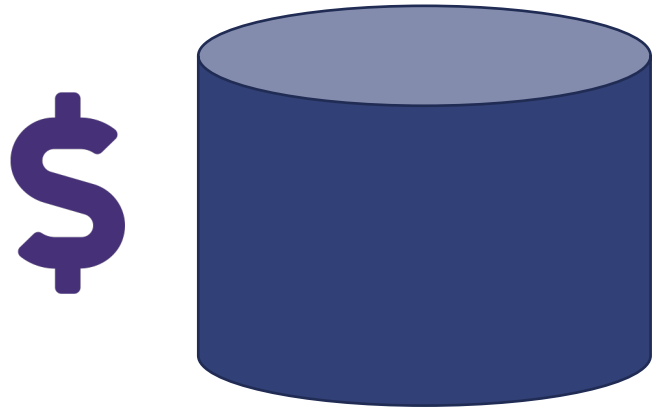


➤ Integration costs (Interfaces, APIs, Environment, ...)



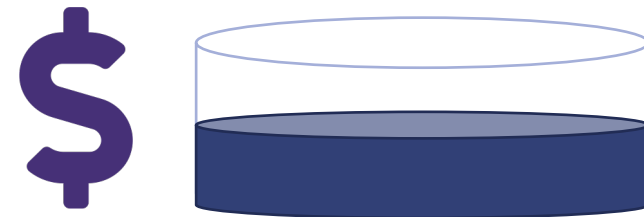
Proprietary

- Monopoly, high dependency



Open Source

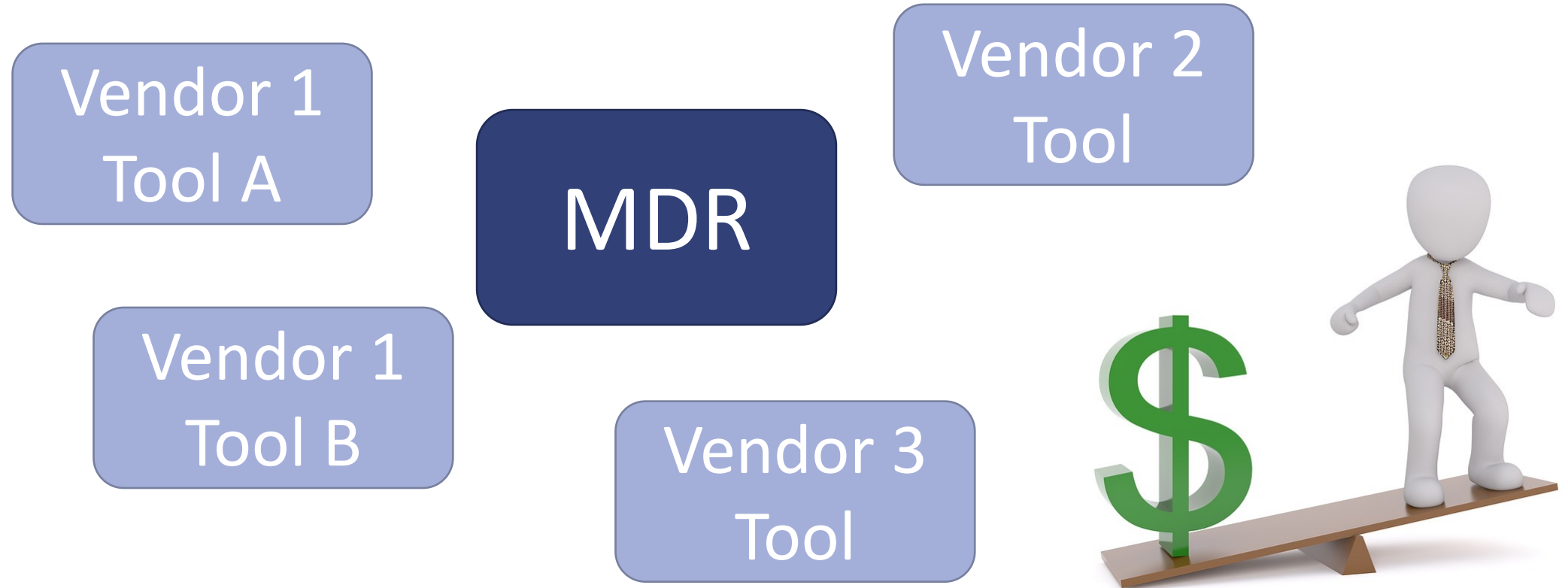
- Typically generic designs
- Adoption opportunities



Money, Money, Money



➤ Integration MDR (Metadata Repository)



Money, Money, Money

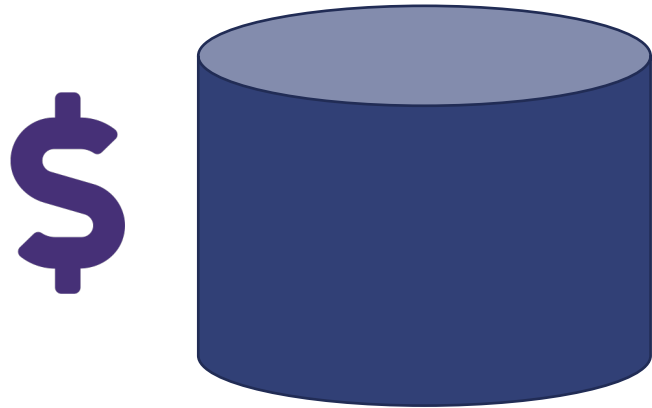


➤ Enhancements - features / functionalities / APIs



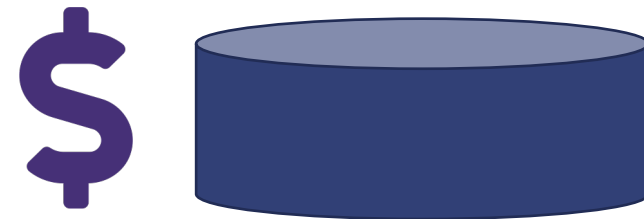
Proprietary

- Monopoly, high dependency



Open Source

- Community
- Own/contracted developer



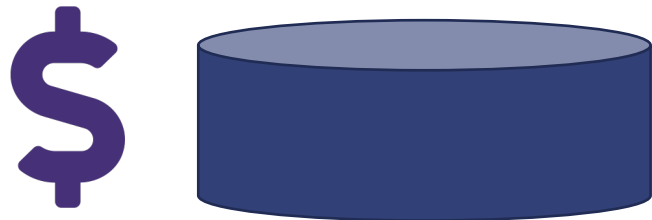
Money, Money, Money



➤ Training

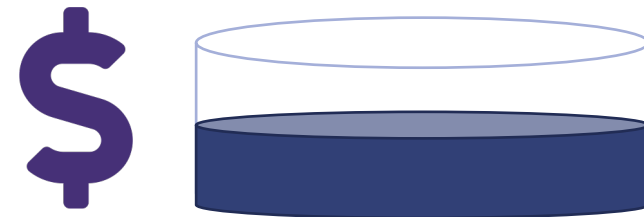
Proprietary

- Vendor
- Own trainings



Open Source

- Community
- Own trainings
- “Standard” savings



Money, Money, Money



- Development
 - Validation
 - Environment
 - Maintenance
 - Integration
 - Enhancements
 - Training
-

Money, Money, Money



- Development
- Validation
- Environment
- Maintenance
- Integration
- Enhancements
- Training



High cost
dependency

Money, Money, Money



- Meaning for open source
 - Early contribution in planning development
 - Save later maintenance & integration



CORE - Open Source Project



CDISC 360° Project

Money, Money, Money



➤ Proprietary Software



Dependency



Money, Money, Money



- Open Source Software



Fairness & More



- Fairness (proprietary software)
 - High dependency on vendor
 - Avoid small/innovative ones due to risk of “sell/out of business”

- Prices / Processes (e.g. reuse anonymized data)
 - Monopoly
 - Process-dependency

- No Transparency
 - E.g. different companies -> same request, pay twice (interfaces)



Fairness & More



- Fairness (open software)
 - Expecting free-time investments
 - Expecting quality at low cost
 - Expecting OTHERs to do



Fairness & More



- Join Open Source Project
- Create Open Source Projects
- Use Open Source



Fairness & More



- Open Source
 - Findable
 - Accessible
 - Interoperable
 - Reusable



Open Source is FAIRest!

Fairness & More



- Main advantage of Open Source

Collaboration!



Fairness & More



Collaboration!

- Common understanding
- Common processes
- Common tools & interfaces

- Open discussions throughout industry
- Going the next step -> implementation
- Standard datasets not sufficient
- Authority acceptance



Fairness & More



➤ Think about cost

Environment



SLA

Interfaces

Initial/Monthly Costs

Fairness & More



- Total Cost for Proprietary
 - Costs if done as Open Source (on your own)
 - Costs Open Source Collaboration
-

Fairness & More



➤ Think about opportunities

Feedback



Common SOPs /
Best practices ...

Connecting Tools



Enhancements

Authority Acceptance

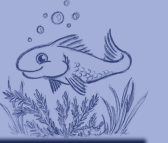
Fairness & More



- Open Source is THE solution
- More initiatives
- More projects
- Huge interest



Questions?



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Single Day Event

Katja Glaß, Katja Glass Consulting
Part Two

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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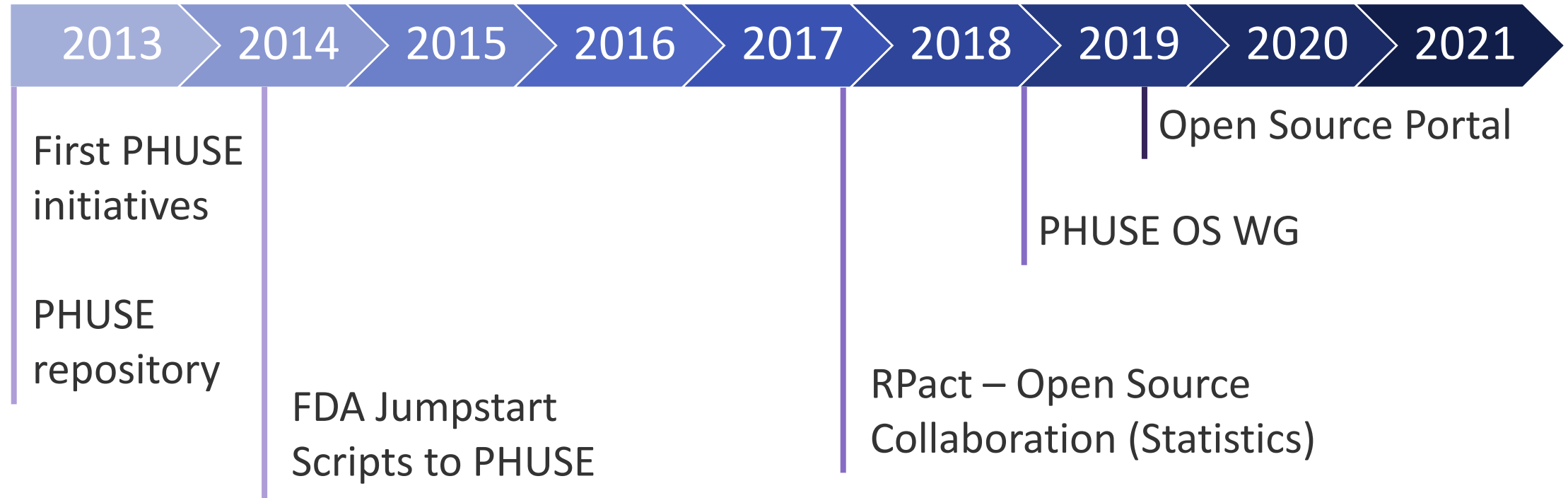
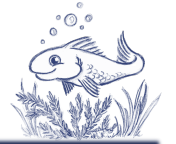


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History



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

BOOOOOOOOM!

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°

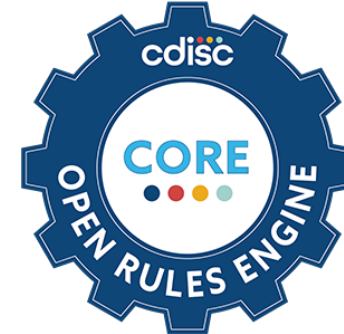
discussions, collaborations

➤ 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)



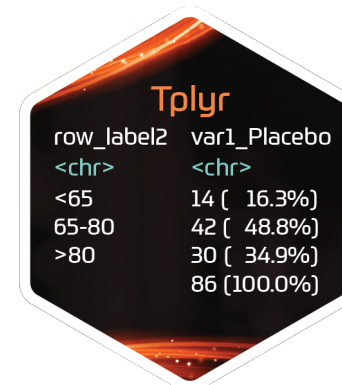
Universe of R



➤ 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
-

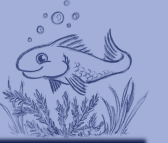
Summary



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



Questions?



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