



# Introducing CAMIS

Comparing Analysis Method Implementations in Software

Chi Zhang, PhD - on behalf of CAMIS WG

UseR! 2024 2024.7.10











Co-lead of CAMIS project since 2024.01











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Statistician and part-time lecturer at Faculty of Medicine, University of Oslo











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R developer, use Quarto for various things - that's another story!











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Today: **CAMIS** 











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PHARMA

# The future of pharma is open source

Open source is changing how drug development happens. Clinical teams are making better decisions, working through clinical trials more confidently, are bringing life-changing drugs to market faster.

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PRODUCTS ~ SOLUTIONS ~ LEARN & SUPPORT ~

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September 2023

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Not sure about SAS, but I can help with the R part - and they use quarto!



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Increase understanding and awareness of **analysis result discrepancies** across software (R, SAS, Python etc)

Demonstrate the methodology through examples, document in open GitHub repository

Repository location: https://psiaims.github.io/CAMIS/



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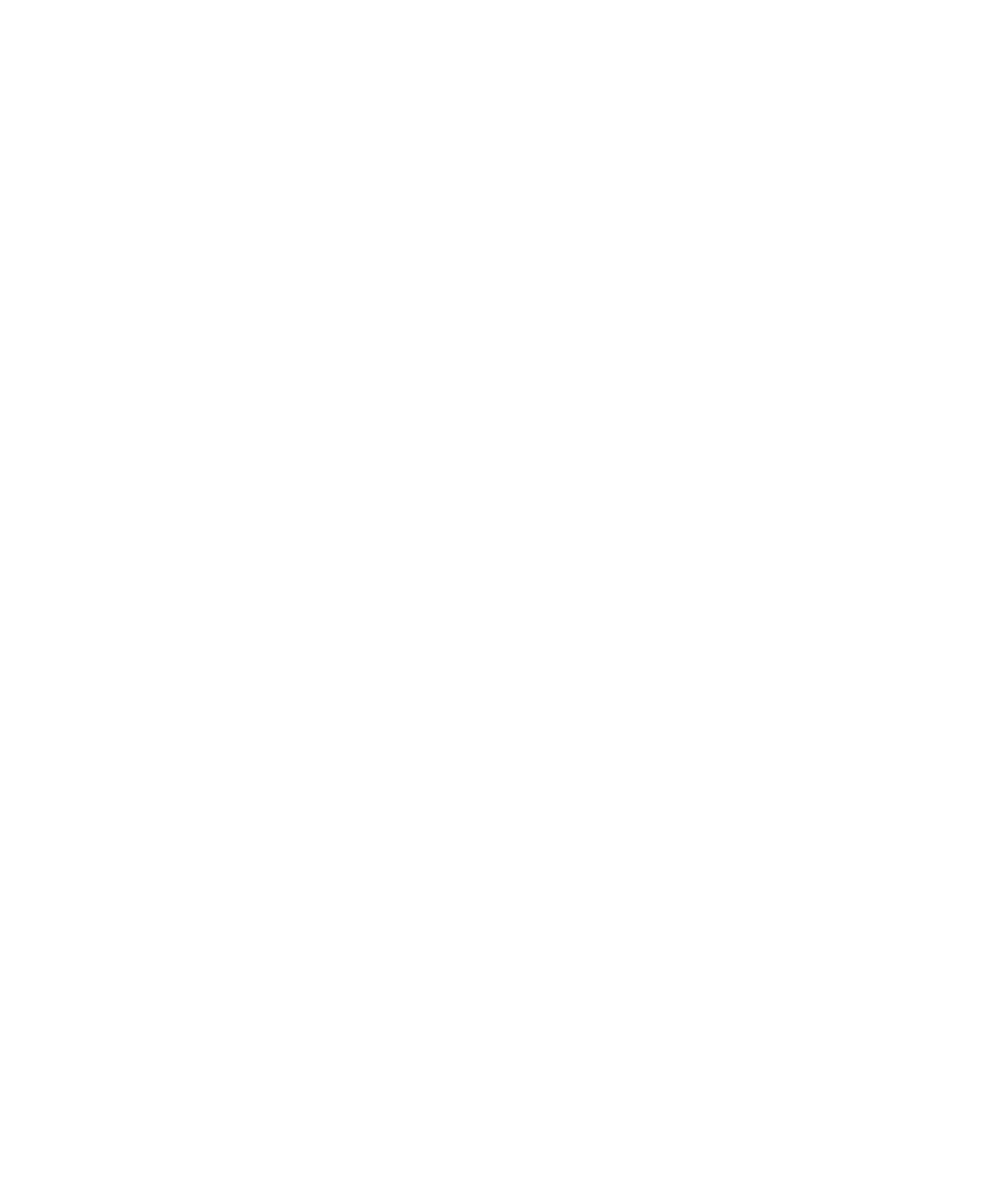
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. prtesti 1000 0.123 0.13

One-sample test of proportion			x: Number of obs = 1006		
	Mean	Std. err.	[95% conf. interval]		
х	.123	.0103861	.1026436 .1433564		
p = proport H0: p = 0.13	ion(x)		z = -0.6582		
Ha: p < <b>0.1</b> Pr(Z < z) = <b>0</b> .		Ha: p != 0.13 Pr( Z  >  z ) = 0.5104	Ha: p > <b>0.13</b> Pr(Z > z) = <b>0.7448</b>		

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What if the p-values differ around 0.05?

```
round(1.5) =
```

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round(1.5) = \frac{\text{round}(1.5)}{[1] 2}
```

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```
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[1] 2

round(0.5) =
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```
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[1] 2

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[1] 0
```

```
> round(1.5)
round(1.5) =
                   [1] 2
                  > round(0.5)
round(0.5) =
                   [1] 0
                  > janitor::round_half_up(0.5)
                  [1] 1
                  > round(1.55)
round(1.55) =
                  [1] 2
round(1.55, digits = 1) =
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round(0.5) =
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round(1.55) =
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round(1.55, digits = 1) =
              > round(1.55, digits = 1)
              [1] 1.6
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In R, round() to the nearest even; in SAS, round() round half up

Pharmaverse blog has an article on this topic

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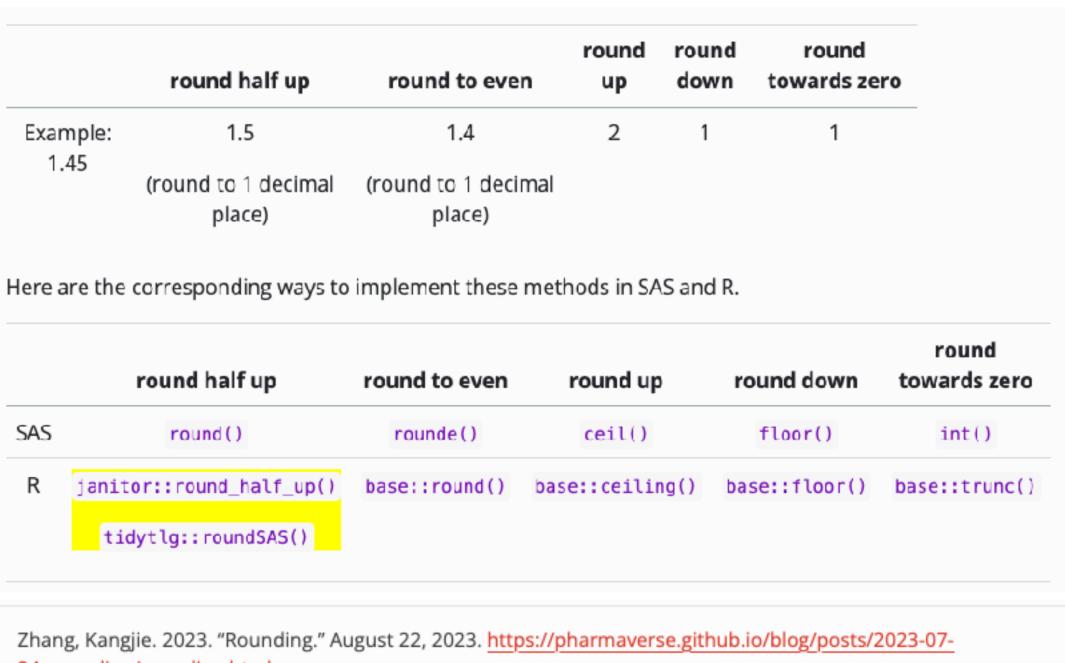
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24\_rounding/rounding.html.







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In **public sector**: teaching, medical research and public health, SPSS / stata (even excel!) vs R, python







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Do we get the same results? Which is correct, Why do they differ?







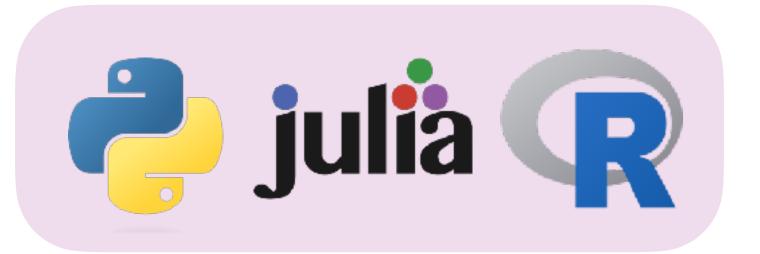
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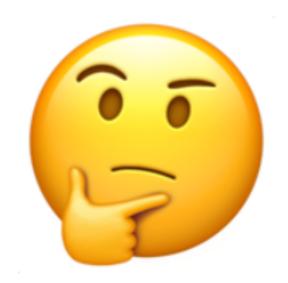
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**Reproducibility** challenges already exist even when there's only one software (set seed, package versioning, inaccessible sensitive data for revision, ...)

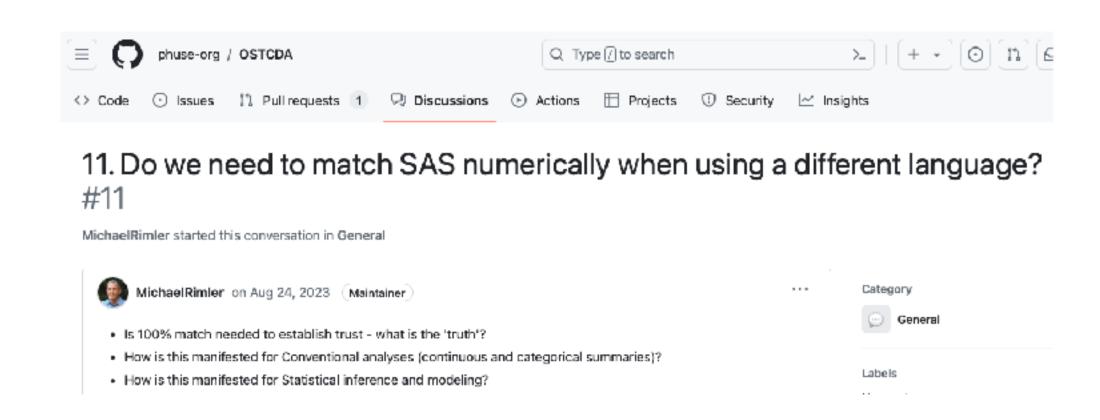






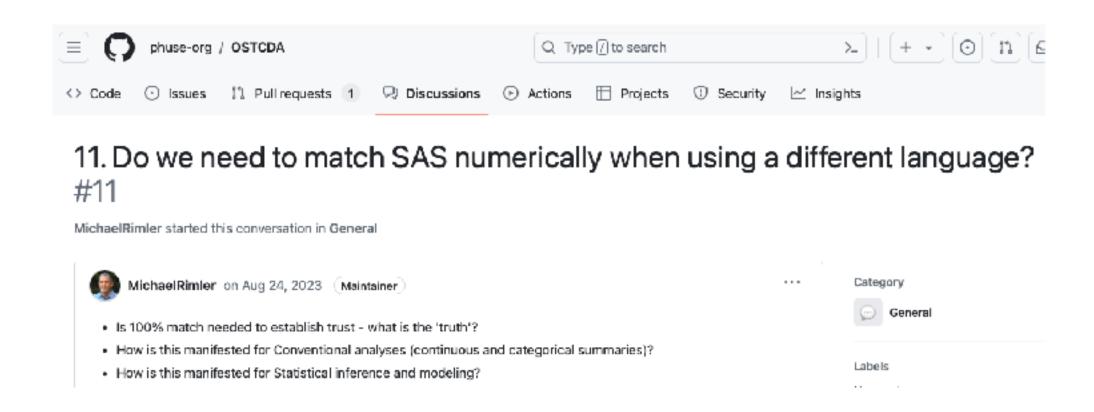


Open Source Technology in Clinical Data Analysis & ≪



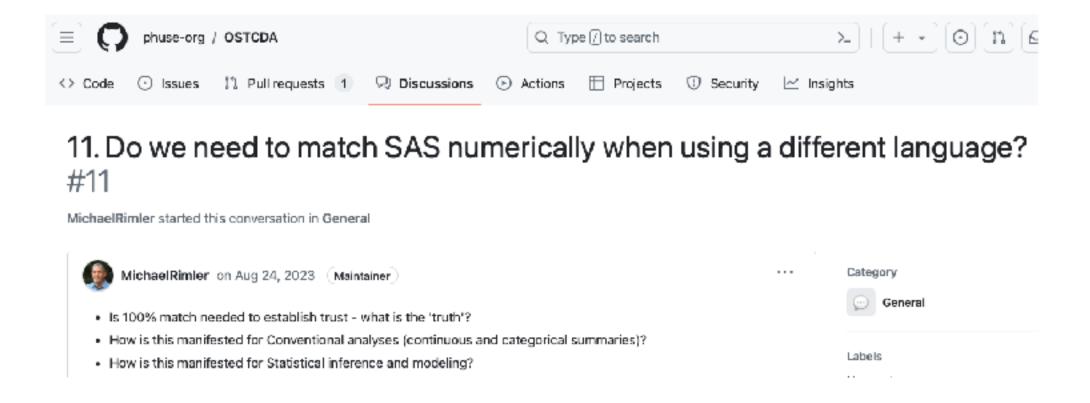


Open Source Technology in Clinical Data Analysis & ≪





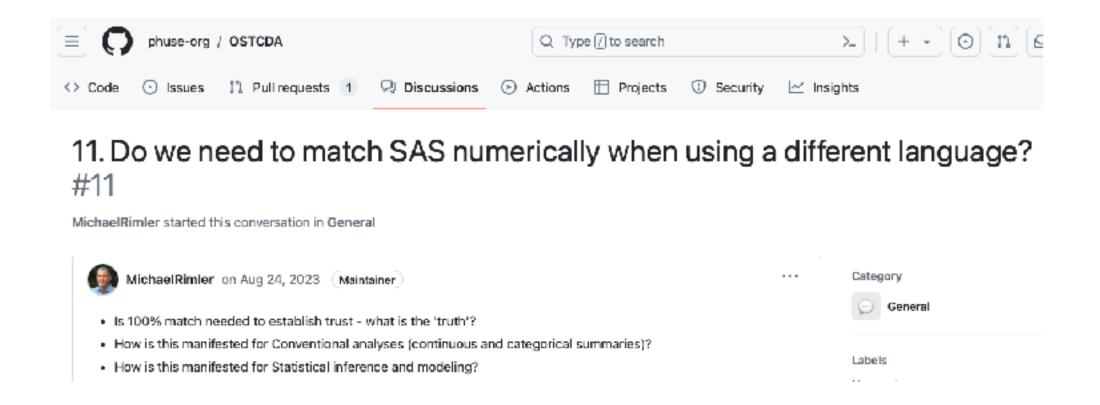
Open Source Technology in Clinical Data Analysis & ≪



**Accuracy, reproducibility, traceability** (Modernization of Statistical Analytics Framework)



Open Source Technology in Clinical Data Analysis & <\$

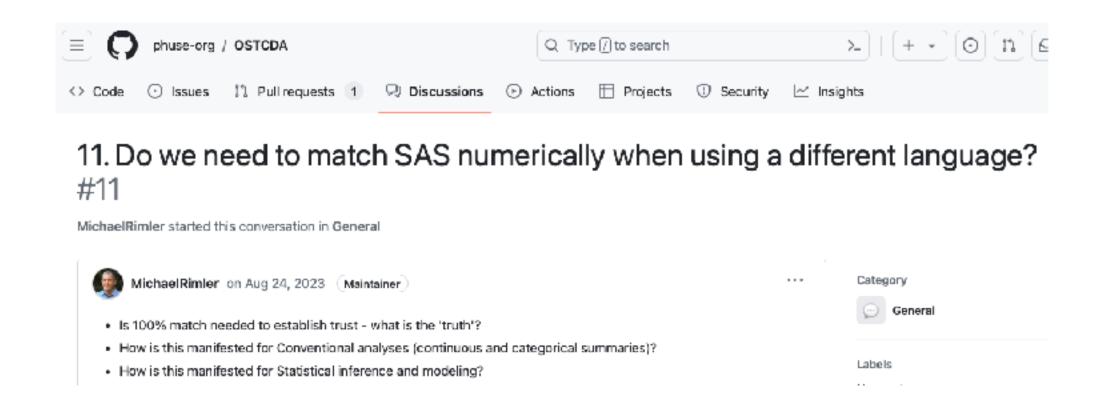


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**Validation**: establish **documented evidence** which provides a high degree of assurance that procedures **consistently** produce a product meeting its predetermined specifications



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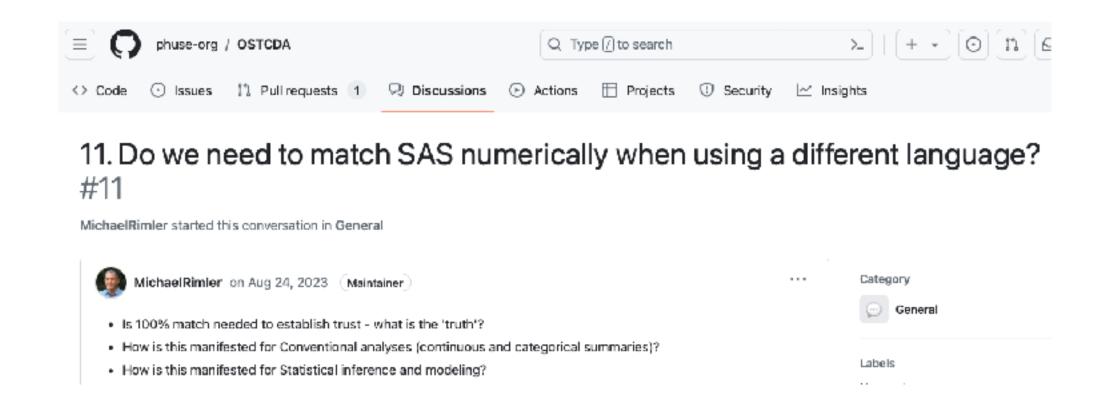
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# Rounding In CAMIS

round(0.5) = 
$$\frac{\text{round}(0.5)}{[1]}$$

round(1.55) = 
$$\frac{\text{round}(1.55)}{[1] 2}$$

Methods		R	SAS	Python	Comparison
Summary Statistics	Rounding	<u>R</u>	SAS	<u>Python</u>	R vs SAS
	Summary statistics	<u>R</u>	SAS	Python	R vs SAS
	Skewness/Kurtosis	<u>R</u>	SAS	<u>Python</u>	R vs SAS

### **R v SAS rounding**

### Rounding; R and SAS

On comparing the documentation of rounding rules for both languages, it will be noted that the default rounding rule (implemented in the respective language's round() function) are different. Numerical differences arise in the knife-edge case where the number being rounded is equidistant between the two possible results. The round() function in SAS will round the number 'away from zero', meaning that 12.5 rounds to the integer 13. The round() function in Base R will round the number 'to even', meaning that 12.5 rounds to the integer 12. SAS does provide the rounde() function which rounds to even and the janitor package in R contains a function round\_half\_up() that rounds away from zero. In this use case, SAS produces a correct result from its round() function, based on its documentation, as does R. Both are right based on what they say they do, but they produce different results (Rimler, M.S. et al.).

#### References

Rimler M.S., Rickert J., Jen M-H., Stackhouse M. Understanding differences in statistical methodology implementations across programming languages (2022, Fall). ASA Biopharmaceutical Report Issue 3, Volume 29. Retrieved from <a href="https://higherlogicdownload.s3.amazonaws.com/AMSTAT/fa4dd52c-8429-41d0-abdf-0011047bfa19/UploadedImages/BIOP%20Report/BioPharm\_fall2022FINAL.pdf">https://higherlogicdownload.s3.amazonaws.com/AMSTAT/fa4dd52c-8429-41d0-abdf-0011047bfa19/UploadedImages/BIOP%20Report/BioPharm\_fall2022FINAL.pdf</a>

## Where are we now,

where do we go next?

Contributors 18

Contributors 18

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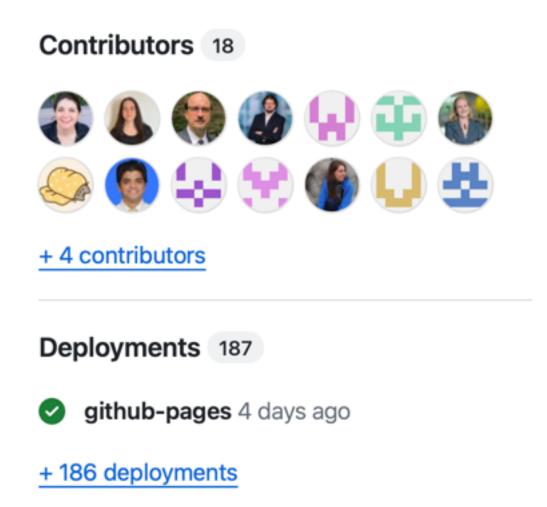
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Many participants on the monthly update meetings (might not directly contribute to the content on GH, but in other ways - discussion, collaboration, presentation)



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### **Motivation**

The goal of this project is to demystify conflicting results between software and to help ease the transitions to new languages by providing comparison and comprehensive explanations.

On this page
Introduction
Motivation
Repository

### Repository

The repository below provides examples of statistical methodology in different software and languages, along with a comparison of the results obtained and description of any discrepancies.

Methods		R SAS	Python	Comparison
Summary Statistics	Rounding	R SAS	Python	R vs SAS
	Summary statistics	R SAS	Python	R vs SAS
	Skewness/Kurtosis	R SAS	Python	R vs SAS
General Linear Models	One Sample t-test	R SAS	Python	R vs SAS
	Paired t-test	R SAS	Python	R vs SAS
	Two Sample t-test	R SAS	Python	R vs SAS
	ANOVA	R SAS		R vs SAS
	ANCOVA	R SAS	Python	R vs SAS
	MANOVA	R SAS	Python	R vs SAS
	Linear Regression	R SAS		R vs SAS
Generalized Linear Models	Logistic Regression	R SAS		
	Poisson/Negative Binomial Regression	<u>R</u>		

SAS vs R

Since CAMIS group has a focus on pharmaceutical industry, the **comparisons** are mostly in SAS vs R

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Example page: one sample t-test

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### One Sample t-test Comparison

The following table shows the types of One Sample t-test analysis, the capabilities of each language, and whether or not the results from each language match.

Analysis	Supported in R	Supported in SAS	Results Match	Notes
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### **Comparison Results**

### **Normal Data**

Statistic	t.test()	proc_ttest()	PROC TTEST	Match Notes
Degrees of Freedom	29	29	29	Yes
t value	2.364306	2.364306	2.364306	Yes
p value	0.0249741	0.0249741	0.0249741	Yes

Since CAMIS group has a focus on pharmaceutical industry, the **comparisons** are mostly in SAS vs R

Example page: one sample t-test

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Talk recording and slides she gave on *R/ Medicine 2024* is available on CAMIS website

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### 

Closed 37 issues

187 deployments of the website

Still many open issues - we need your help!

	Author ▼
O Pearson's/ Spearman's/ Kendall's Rank Python #216 opened 3 weeks ago by seemaniabhilipsa	
<ul> <li>Website: dissertation info documentation</li> <li>#215 opened 3 weeks ago by andreaczhang 2 of 4 tasks</li> </ul>	
MANOVA Python #208 opened on May 21 by seemaniabhilipsa	
Overall structure #200 opened on May 6 by therneau	
Survey Statistics - Example/Comparison (Python) Python #185 opened on Apr 15 by michaelwalshe	
add more contribution guidance  #143 opened on Feb 7 by DrLynTaylor	
O Add more information about the version of R running and packated #139 opened on Jan 25 by statasaurus	ige
Other Methods - Machine learning Comparison R SAS #67 opened on Mar 20, 2023 by statasaurus	
Other Methods - Causal inference Comparison R SAS	

Quarto has been the **publishing and collaboration** tool we use

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Easy to write articles, render results for multiple language (R, python)

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```
proc freq data = test_case;
weight Count;
tables treatment * Weight / chisq fisher;
exact or;
run;
```

#### Output:

#### The FREQ Procedure Table of treatment by Weight Frequency Percent Row Pct Col Pct Total 10.33 18.31 28.64 36.07 63.93 36.07 25.66 18.31 53.05 25.66 74.34 63.93 74.34 152 28.64 71.36 100.00

#### Statistics for Table of treatment by Weight

Statistic	DF	Value	Prob
Chi-Square	1	2.3072	0.1288
Likelihood Ratio Chi-Square	1	2.2490	0.1337
Continuity Adj. Chi-Square	1	1.8261	0.1766
Mantel-Haenszel Chi-Square	1	2.2964	0.1297
Phi Coefficient		0.1041	
Contingency Coefficient		0.1035	
Cramer's V		0.1041	

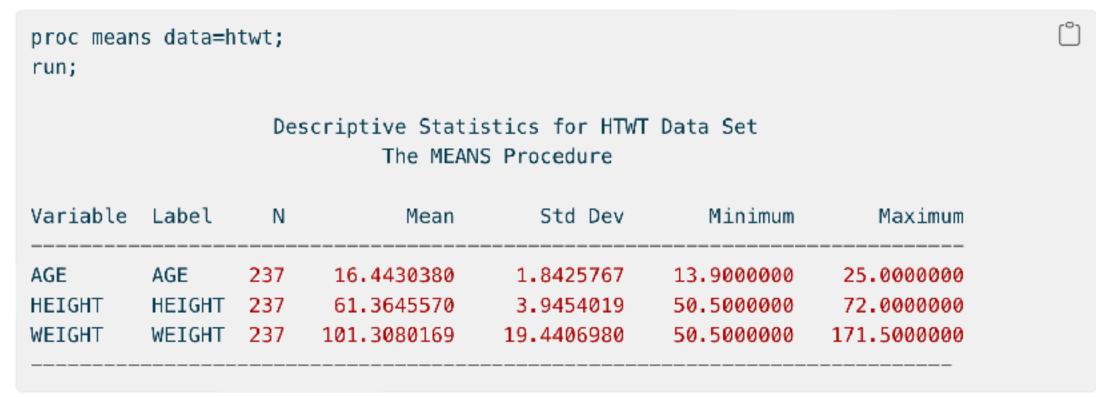
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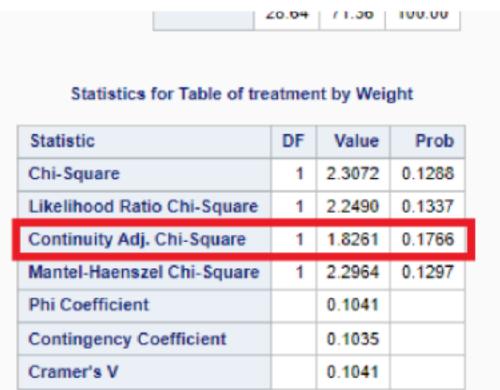
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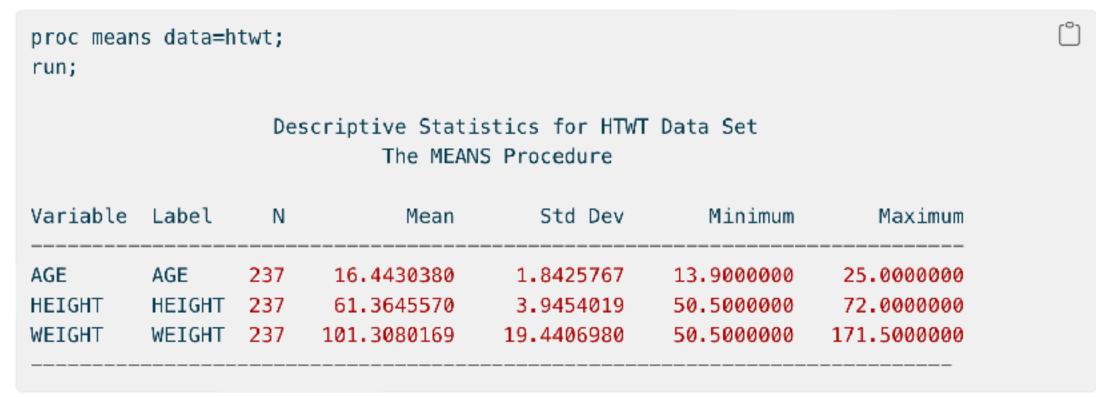
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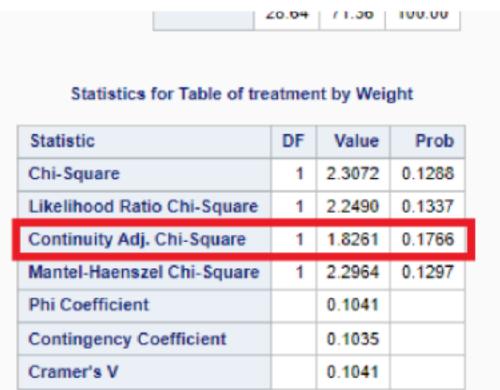
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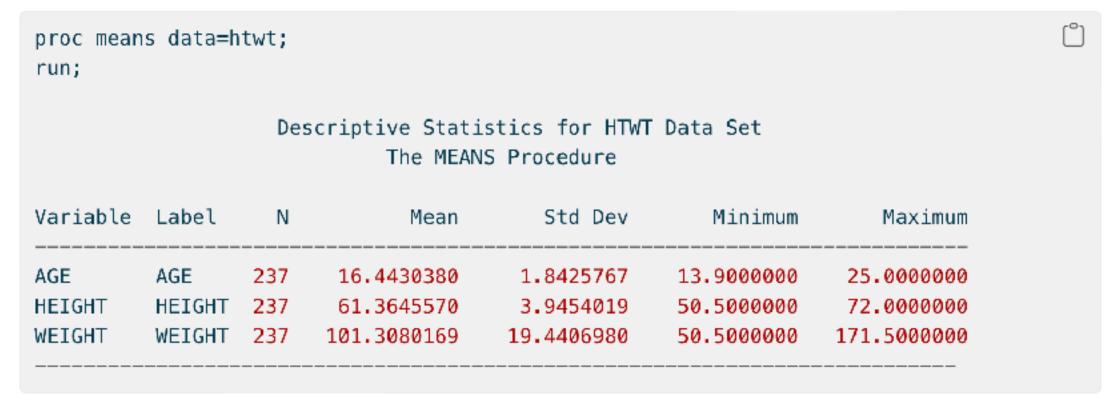
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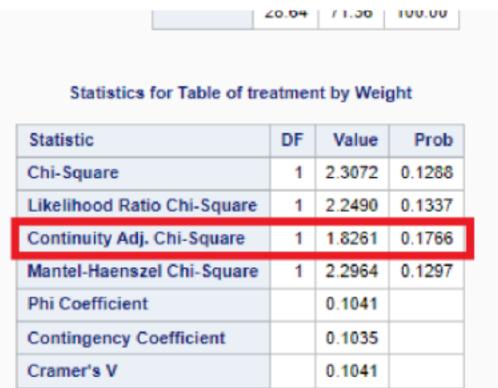
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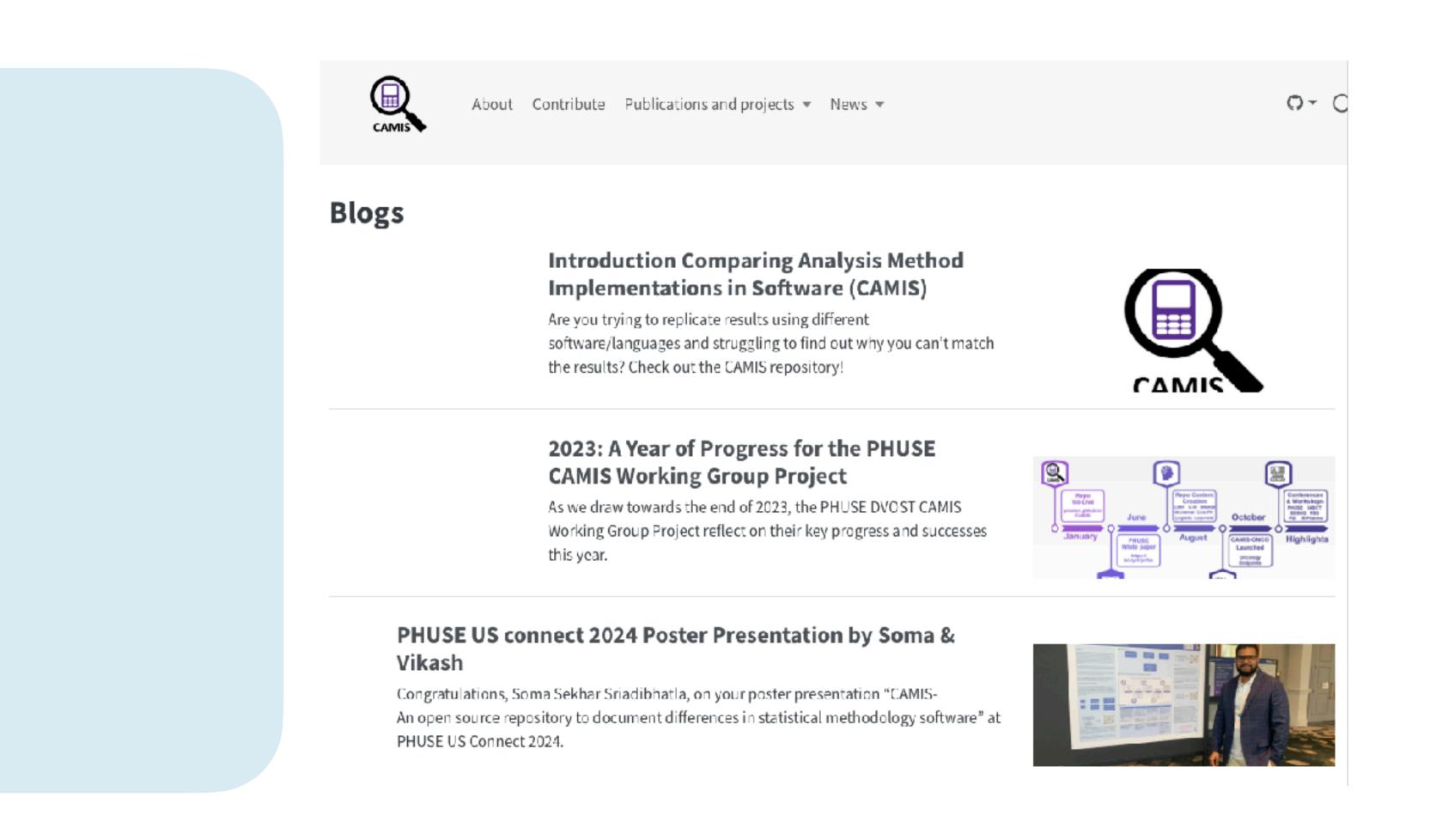
**R packages** and versioning: we're working on a solution with **renv**, getting help from posit!

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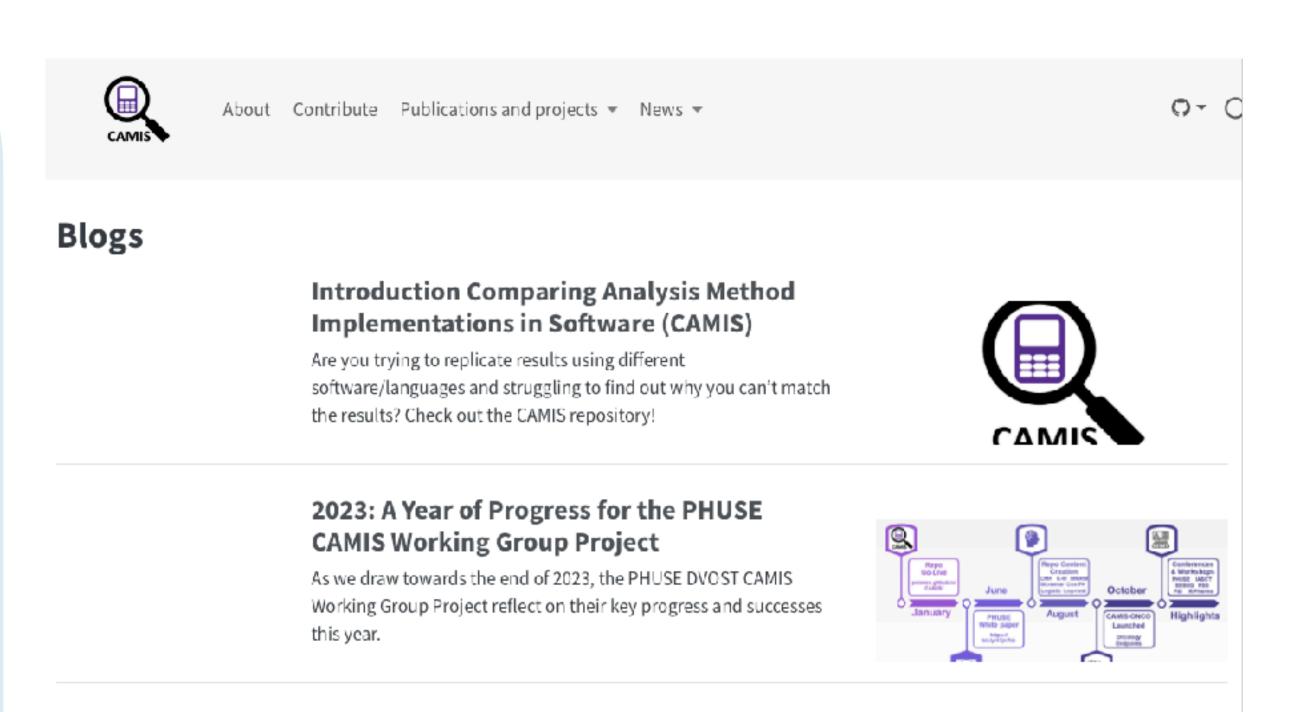
Output:







4 co-leads: Lyn Taylor (Parexel), Christina Fillmore (GSK), Harshal Khanolkar (Novo Nordisk), Chi Zhang (University of Oslo)



PHUSE US connect 2024 Poster Presentation by Soma &

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An open source repository to document differences in statistical methodology software" at

Vikash

PHUSE US Connect 2024.

Vikash

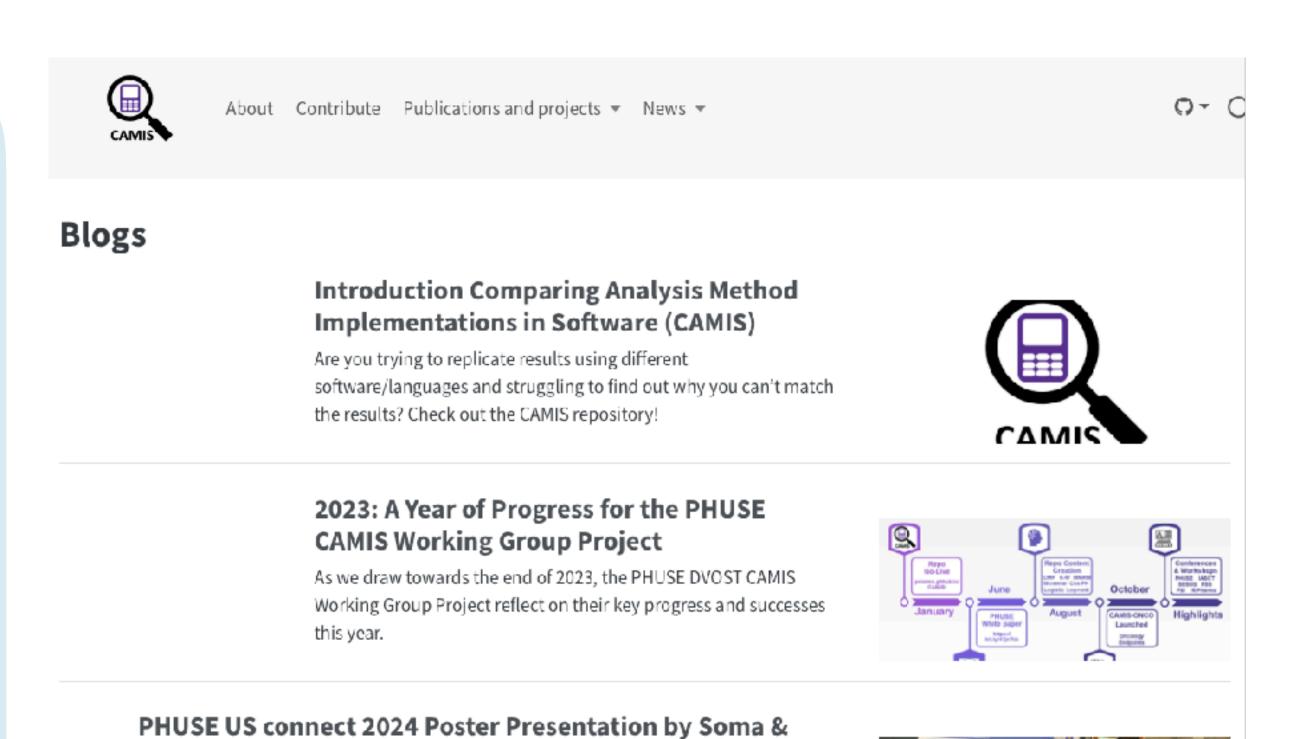
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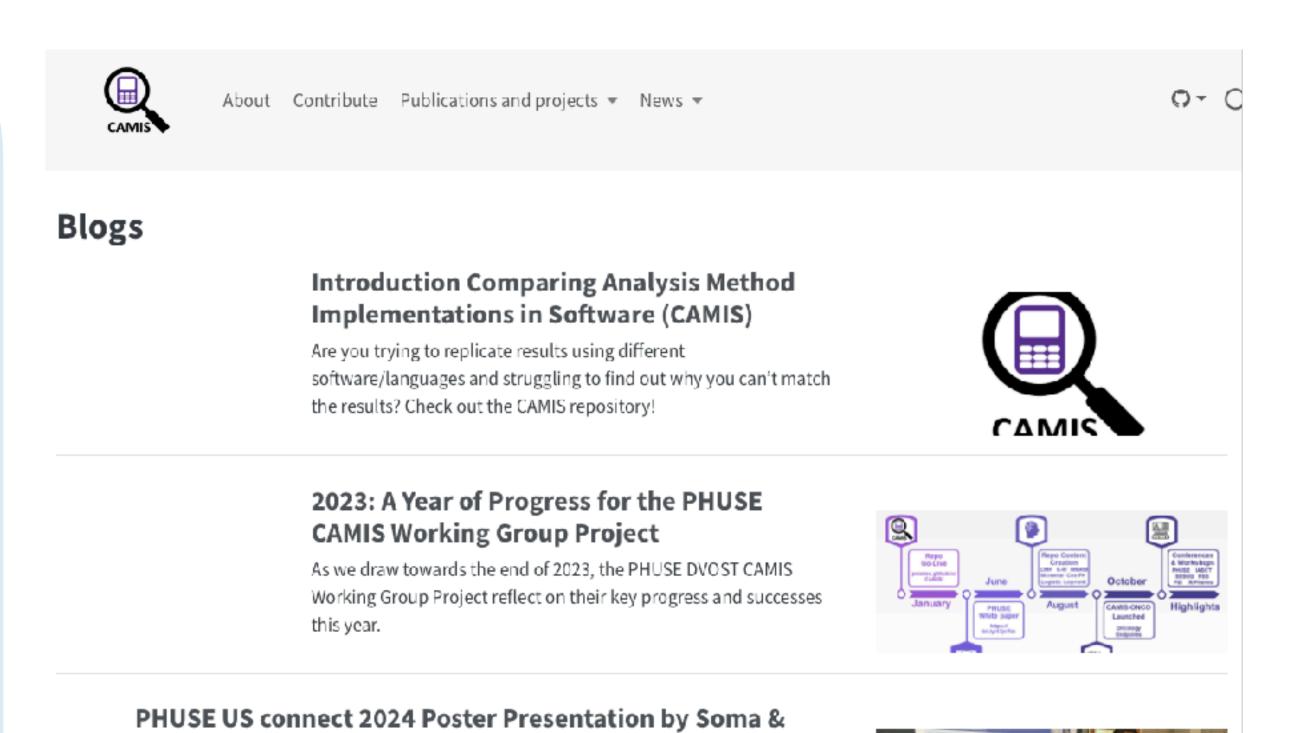
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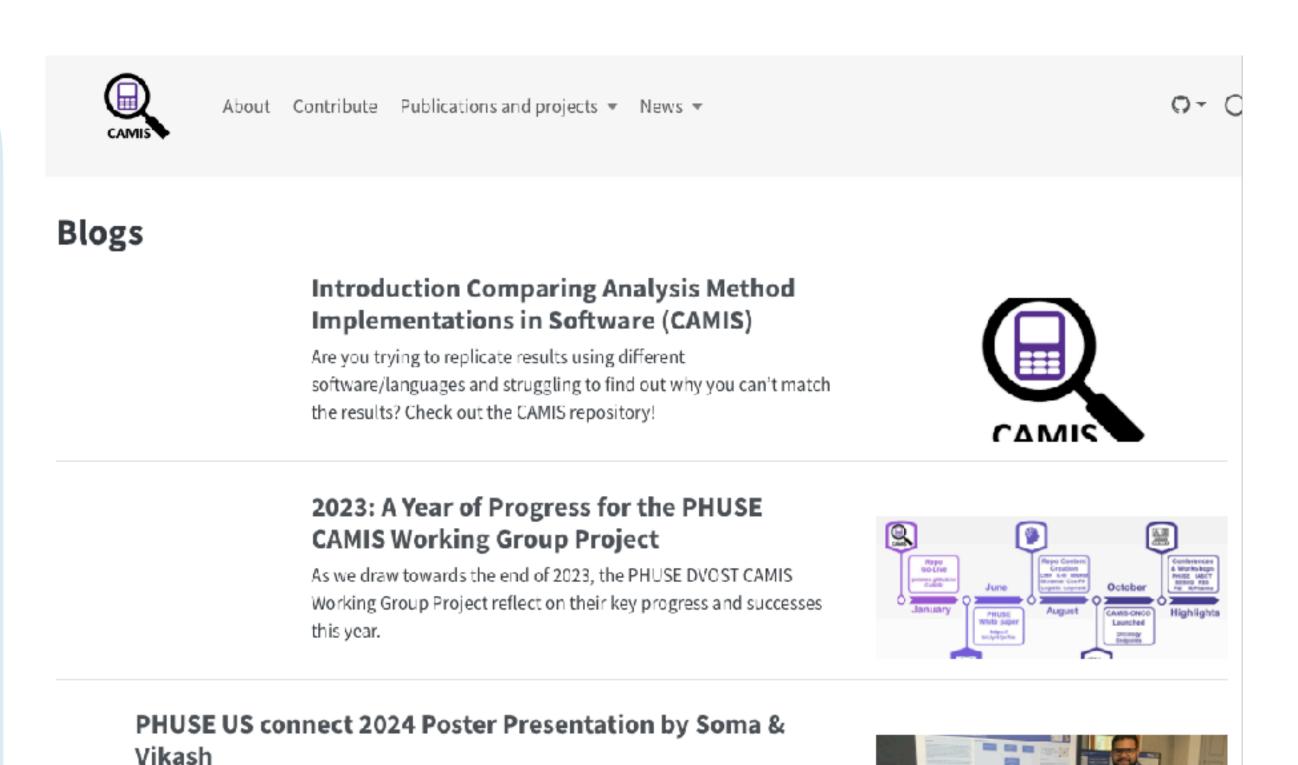


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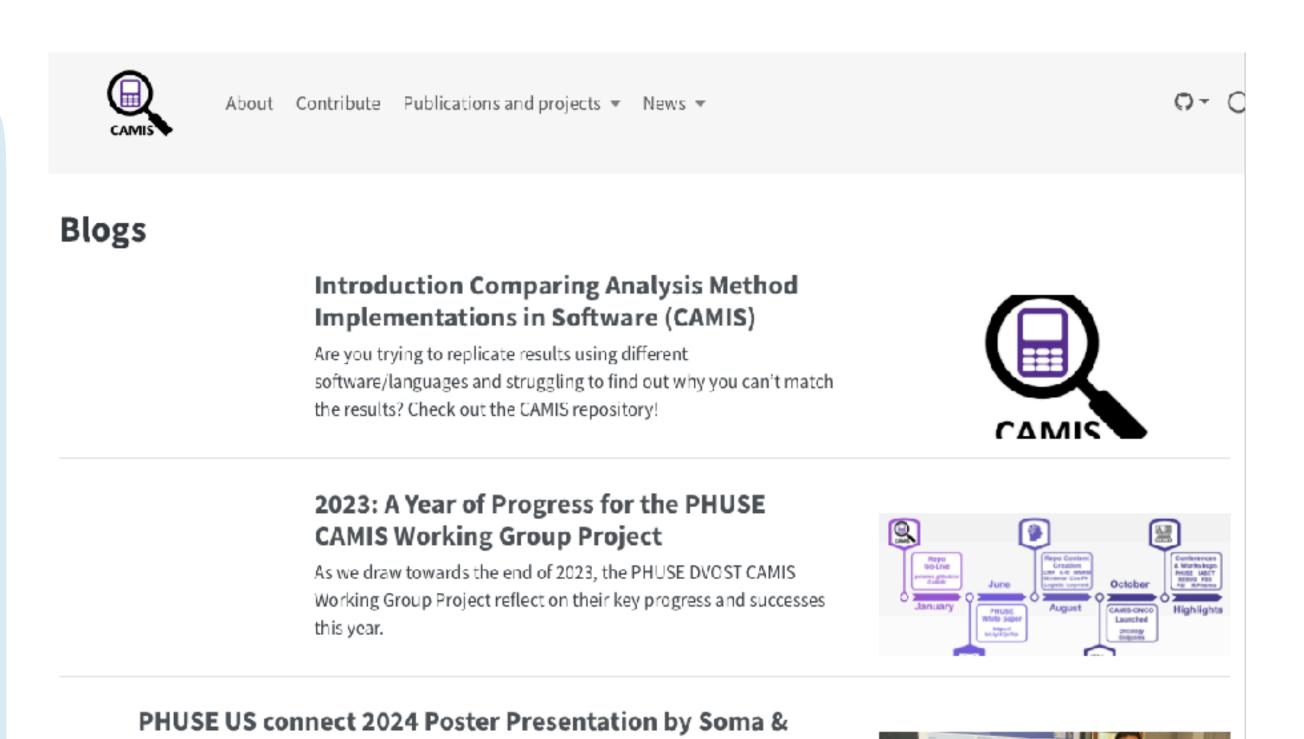
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Conference name	Date (2024)	Location	Name Attending	Details	Website
RSS Local Group Seminar	28 Feb	Sheffield, England	Lyn Taylor	Slides	RSS
phuse US Connect	25-28 Feb	Bethesa, Maryland, USA	Soma Sekhar Sriadibhatla, Vikash Jain, Brian Varney	<u>Poster</u>	Connect
phuse chapter connect	03 APR	Bangalore	Harshal Khanolkar		
phuse/FDA CSS	3-5 June	Silver Spring Maryland, USA	Mike Stackhouse	CAMIS Discussion	CSS
R/Medicine	10-14 June	Online	Agnieszka Tomczyk, Lyn Taylor	Part1 and Part2 and slides	R/Medicin e 2024
UseR!	8-11 July	Salzburg, Austria	Chi Zhang	Presentation	<u>useR!</u> 2024
phuse EU	11-13 Nov	Strasbourg, France	Agnieszka Tomczyk, Christina Fillmore	Presentation	PHUSE EU Connect



Philip Bowsher · 1st

Director, Health and Life Sciences Industry Leader at Posit/RStudio PBC Ta... 3w • Edited • •

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Many organizations (Roche, Novo Nordisk, GSK etc.) are keen to use open source for Clinical Study Reports and to generate TFLs in the regulatory space.

One challenge has been observing differences across languages especially for complex TFLs.

Enter "Comparing Analysis Method Implementations in Software" CAMIS!!

The goal of CAMIS is to help understand the source of any differences between software and provide comparison and comprehensive explanations.

The team has collected and documented many SAS & R differences such as:

Repeated Measures Analysis:

https://lnkd.in/ggfTFqjP

Rounding:

https://lnkd.in/gZtFZrps



23 comments • 38 reposts

Full discussion and post:





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CON You and 438 others

23 comments • 38 reposts



Stephen Senn • 2nd Statistical Consultant

What a fascinating and important initiative. A classic paper is this by Reinhard Bergmann et

all https://www.tandfonline.com/doi/abs/10.1080/00031305.2000.1 0474513 . Another issue that surfaces is that different packages can use different approaches to parameterisation, especially in the presence of interactions. This can mean that they disagree in estimation even though they agree in prediction. The long standing debate on Type III v Type II SS is related to this. See discussion in https://journals.sagepub.com/doi/10.1177/00928615000340022 2 of an example of Christy Chiung-Stein's and Donald Tong.



Different Outcomes of the Wilcoxon—Mann—Whitney Test from Different St...

tandfonline.com

Like · Ĉ♥ 13 | Reply · 4 Replies

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PHUSE Open Source Technology in Clinical Data Analysis WG

https://github.com/phuse-org/OSTCDA/discussions/

They have a community call to discuss relevant topics

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#### **4 Documenting Trust**

### 4.1 How do you document your trust in an open source solution?

- How do we have document our trust that an open source solution is accurate?
- How do we know if a third-party will accept our documentation of trust?

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Open Source Technology in Clinical Data Analysis ৬ <

Q

#### Preface

- 1 What is Open Source?
- 2 Why Open Source?
- 3 Establishing Trust
- 4 Documenting Trust
- 5 Cost of Open Source
- 6 Regulatory Acceptance
- 7 GxP Compliance
- 8 User Support
- 9 User Development
- 10 Numerical Matching
- 11 OS in the Long Run
- 12 Funding OS

-- -- ---

#### 10 Numerical Matching

### 10.1 Do we need to match SAS numerically when using a different language?

- What if we the same inputs yield similar, but numerically different results?
- · What if we the same inputs yield drastically different results?
- · What is the truth? Which is correct?
- What if SAS and R are equivalent, but a third language yields numerical differences?

#### **10.2 How to Contribute**

Contribute to the discussion here in GitHub Discussions:

Do we need to match SAS numerically when using a different language?

#### 10.3 Guidance

- Provide your thoughts and perspectives
- · Provide references to articles, webinars, presentations (citations, links)
- Be respectful in this community

# Collaboration openstatsware - mmrm

#### R vs SAS MMRM

#### Introduction

In this vignette we briefly compare the mmrm::mmrm, SAS's PROC GLIMMIX, nlme::gls, lme4::lmer, and glmmTMB::glmmTMB functions for fitting mixed models for repeated measures (MMRMs). A primary difference in these implementations lies in the covariance structures that are supported "out of the box". In particular, PROC GLIMMIX and mmrm are the only procedures which provide support for many of the most common MMRM covariance structures. Most covariance structures can be implemented in gls, though users are required to define them manually. lmer and glmmTMB are more limited. We find that mmmrm converges more quickly than other Rimplementations while also producing estimates that are virtually identical to PROC GLIMMIX's.

#### **Convergence Times**

#### **FEV Data**

The mmrm, PROC GLINNIX, gls, lmer, and glmmTMB functions are applied to the FEV dataset 10 times. The convergence times are recorded for each replicate and are reported in the table below.

#### Comparison of convergence times: milliseconds

Implementation	Median	First Quartile	Third Quartile
mmrm	56.15	55.76	56.30
PROC GLIMMIX	100.00	100.00	100.00
lmer	247.02	245.25	257.46
gl5	687.63	683.50	692.45
glmm™B	715.90	708.70	721.57

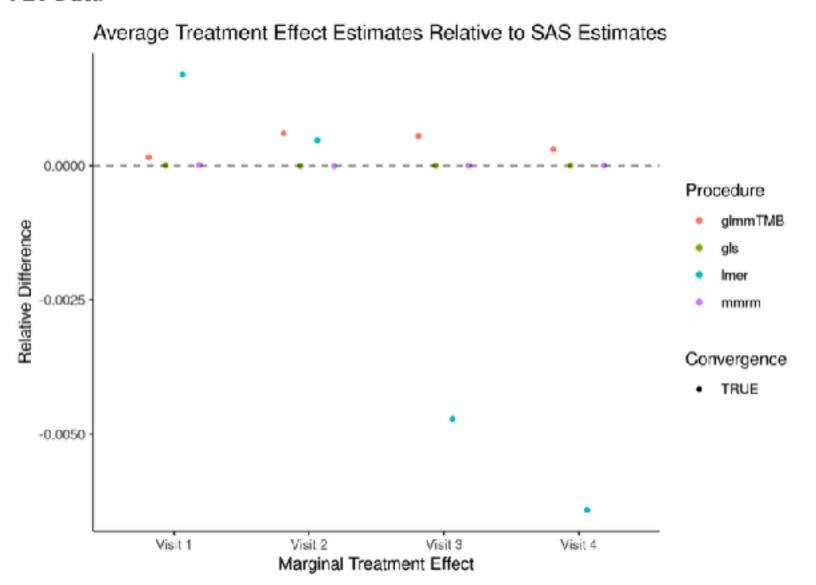
It is clear from these results that mmrm converges significantly faster than other R functions. Though not demonstrated here, this is generally true regardless of the sample size and covariance structure used. mmrm is faster than PROC GLIMMIX.



#### Marginal Treatment Effect Estimates Comparison

We next estimate the marginal mean treatment effects for each visit in the FEV and BCVA datasets using the MMRM fitting procedures. All R implementations' estimates are reported relative to PROC GLIMMIX's estimates. Convergence status is also reported.

#### FEV Data



Possibility to add the Bayesian implementation as well

### Academia - dissertation



	· ·		
Repeated Measures	Linear Mixed Model (MMRM)	R SAS	R vs SAS
	Generalized Linear Mixed Model (MMRM)		
	Bayesian MMRM		
Multiple Imputation - Continuous	MCMC		
Data MAR	Linear regression	<u>R</u>	
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Multiple Imputation - Continuous Data MNAR	Delta Adjustment/Tipping Point		
Data WINAK	Reference-Based Imputation/Sequential Methods		
	Reference-Based Imputation/Joint Modelling		
Correlation	Pearson's/ Spearman's/ Kendall's Rank	<u>R</u>	
Survival Models	Kaplan-Meier Log-rank test and Cox- PH	R SAS	R vs SAS
	Accelerated Failure Time		
	Non-proportional hazards methods		
Sample size /Power calculations	Single timepoint analysis		
	Group-sequential designs		
Multivariate methods	Clustering		
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	PCA		

### Academia - dissertation



We are open to **students, researcher** (academia / industry) who want to team up for dissertation projects

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Example: a comparison of MMRM methodology in SAS and R software (ongoing)

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### Academia - dissertation



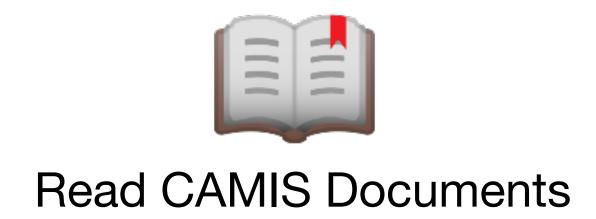
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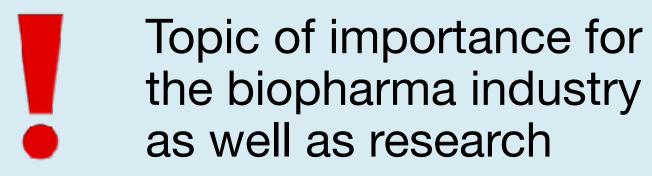
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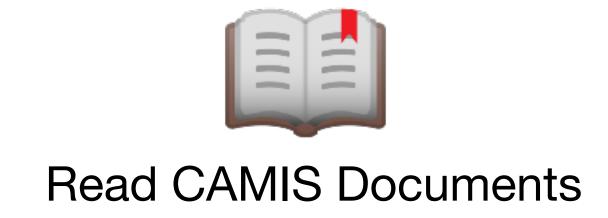
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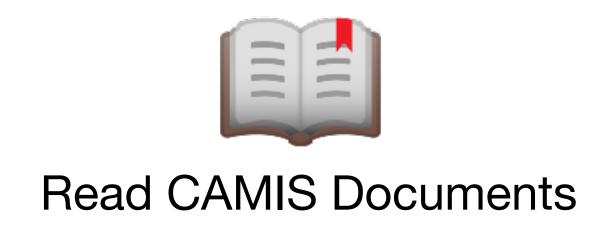








Topic of importance for the biopharma industry as well as research



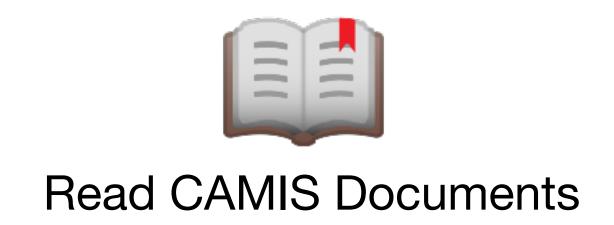


Like to be intellectually challenged and fascinated on something subtle



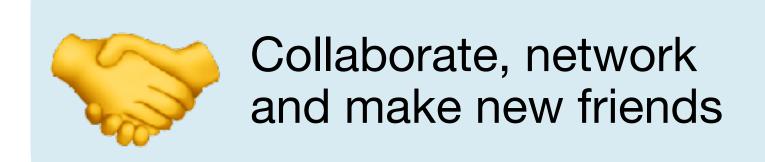


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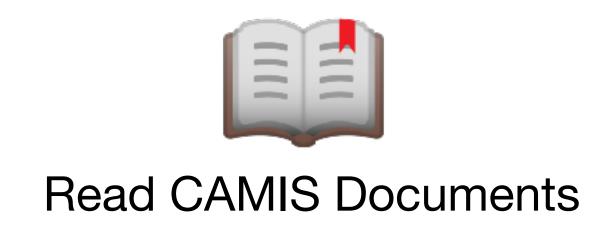
Like to be intellectually challenged and fascinated on something subtle





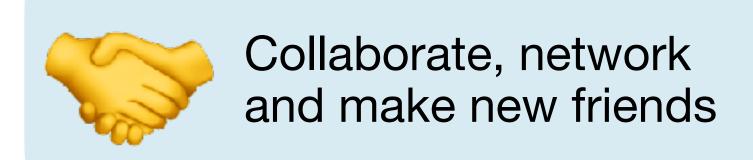


Topic of importance for the biopharma industry as well as research





Like to be intellectually challenged and fascinated on something subtle







Learn new topics on statistics and programming

### How to get started

Contribution guidelines for new contributors

R template for topics to cover

Also we have information for contributors who are **new to GitHub** and Pull Request

Get started: check our **open issues** and comment to indicate your interest, or send us a message

We aim to close 45 issues this year - 37 so far

Help us achieve the goal:)

#### How to contribute to the documentation

Please contribute by **submitting a pull request** (PR) and our team will review it.

#### Adding a new page

If you are adding a new page, please follow our template guideline: R template

Good documentation on data, methods are very much appreciated!

#### First-time contributors

Welcome to CAMIS! Please read this article: <u>Get started</u>, which contains some useful information to help you navigate your first PR submission.

#### Asking for help

If you need any assistance with setting up your workspace, do not hesitate to contact @DrLynTaylor, @statasaurus and @andreaczhang!

□ <b>⊙</b>	Sample size /Power calculations - Group-sequential designs Comparison R  SAS  #59 opened on Mar 20, 2023 by statasaurus
- C	Sample size /Power calculations - Single timepoint analysis Comparison R  SAS  #58 opened on Mar 20, 2023 by statasaurus
_ C	Survival Models - Non-proportional hazards methods Comparison R SAS #57 opened on Mar 20, 2023 by statasaurus
- C	Survival Models - Accelerated Failure Time Comparison R SAS #56 opened on Mar 20, 2023 by statasaurus

### Resources



CAMIS website: <a href="https://psiaims.github.io/CAMIS/">https://psiaims.github.io/CAMIS/</a>

GitHub Repo: <a href="https://github.com/PSIAIMS/CAMIS/">https://github.com/PSIAIMS/CAMIS/</a>

Open issues: <a href="https://github.com/PSIAIMS/CAMIS/">https://github.com/PSIAIMS/CAMIS/</a>

<u>issues</u>

#### **PHUSE** discussions

Do we need to match SAS numerically when using a different language? <a href="https://github.com/phuse-org/OSTCDA/discussions/11">https://github.com/phuse-org/OSTCDA/discussions/11</a>

How to document your trust in an open source solution?

https://phuse-org.github.io/OSTCDA/doc\_trust.html

Please feel free to reach out to the coleads, you can find us on LinkedIn

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Contact

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