openstatsware

Cross-industry, Community-based Development of Open-source Statistical Software

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for the SIG openstatsware

Founding of openstatsware

- 2022: Scientific working group of the American Statistical Association (ASA)
- 2024: Special Interest Group (SIG) of the PSI and EFSPI organizations

- **Main objectives:**
  1. to develop high-quality, open-source statistical software
  2. to promote good software engineering practices
  3. to stimulate collaborations in the statistical community across organizations.

Software

- **Priorities** for software development of statistical methods:
  - missing in the available open-source software
  - fundamental importance in biostatistics
  - relevant for pharmaceutical research.

- **Examples** (with openstatsware lead developers):
  - **R/mmrm** package, which sets a new benchmark for fitting Mixed Models for Repeated Measures (MMRM) in R.
  - **R/brms.mmrm** package, which extends MMRM to Bayesian inference.
  - **R/maicplus** package**,** which implements key statistical models for Health Technology Assessment (HTA) dossier submissions across multiple countries.
  - **Julia/SafetySignalDetection.**jl package, which implements Bayesian Safety Signal Detection by Brock et al. (2023)

Software - R/mmrm (1)

- implements marginal linear model for continuous responses with normal residuals
- models homogeneous or heterogeneous variances and co-variances (groups) across time points, ie unstructured, Toeplitz, AR1, compound symmetry, ante-dependence, spatial exponential
- perform hypothesis testing with Satterthwaite or Kenward-Roger adjustment
- uses restricted (REML) or standard maximum likelihood (ML) inference
- uses weights for observations

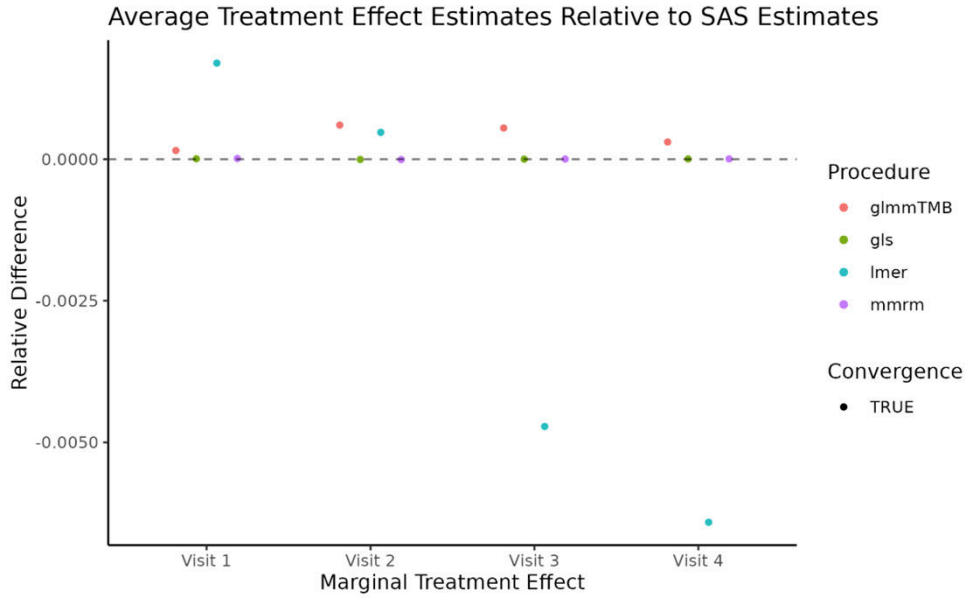
Note: based on current R/mmrm (v0.3.18)

Software - R/mmrm (2)

Dependencies/Integration:

- enables fast and robust model fitting in C++ using R/TMB package
- extracts least square means estimates using R/emmeans package
- integrates with “tidymodels” and “tern” packages

Comparison of R/mmrm with other R packages and SAS:

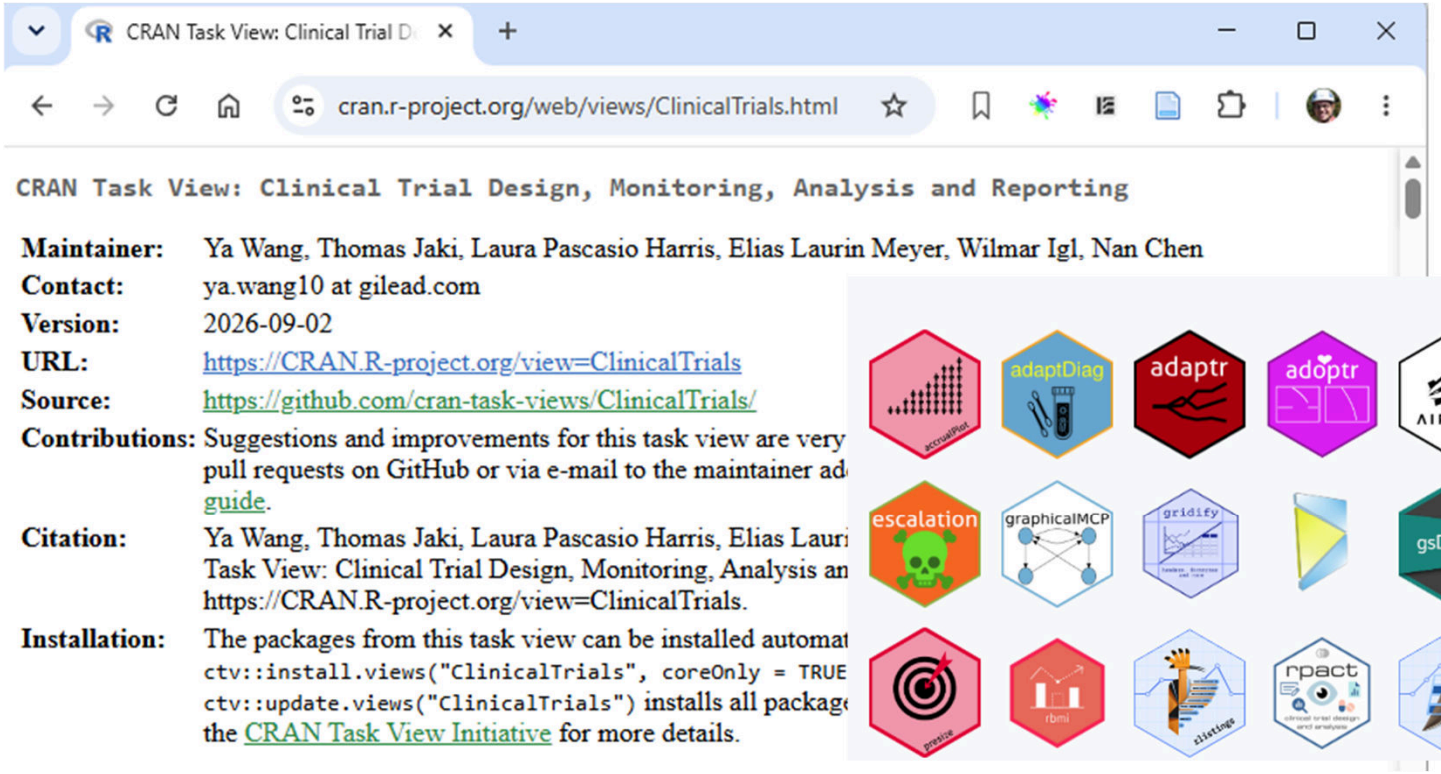


Comparison of convergence times (ms) for example (source)

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
gls	687.63	683.50	692.45
glmmTMB	715.90	708.70	721.57

Software – CRAN Task View “Clinical Trials”

- Maintenance of the CRAN Task View “Clinical Trials” & Task view “Hexwall”
  - Review of new packages
  - Documentation of packages
  - Archiving of legacy packages



Good Software Engineering Practices

- 2023 - 2026: **11x Workshops "Good Software Engineering Practice for R Packages"**
  - 9 locations + 1x online
  - 3 continents
  - course materials publicly available

October 8-9, 2026, Basel, CH: "Good Software Engineering Practice for R Packages"

- 2023 - 2027: Planned and chaired **sessions dedicated to statistical software engineering** at major statistics conferences including
  - CEN2023 (Basel, CH)
  - PSI2025 (London, UK)
  - ISCB2026 (Freiburg, DE)
  - PSI2027 (London, UK, planned)

- 2024: Publication of **openstatsguide** with recommendations for good software engineering practices.

Collaborations

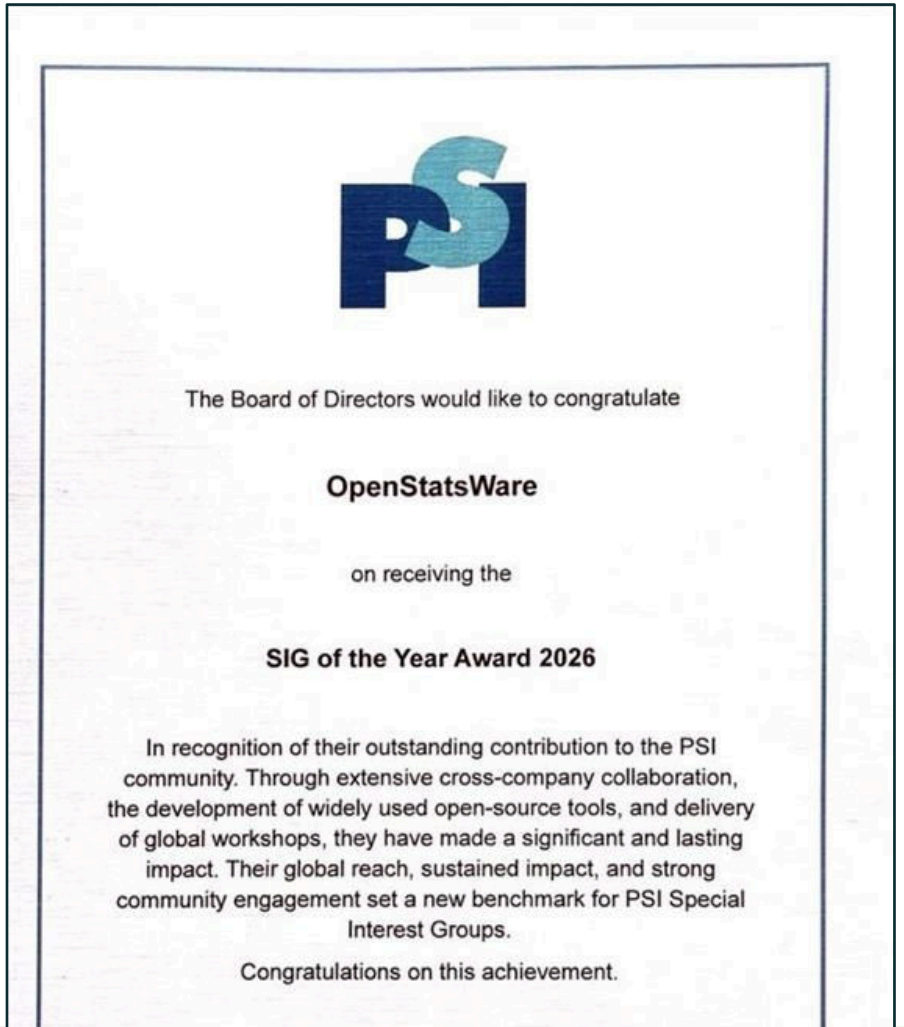
- **Co-chairs:**
  - Daniel Sabanes Bove, RCONIS
  - Ya Wang, Gilead
  - Alessandro Gasparini, Red Door Analytics

- **People**: 64 members
- **Affiliations**: 42 organizations (North America, Europe and Asia)
- **Regional chapters**:
  - US/EU and EU/APAC
  - Communication: 2x video conference per month (1x/month per region)
    - organize the working group
    - discuss ongoing projects
    - share relevant news on statistical methodology and software engineering

- **Code repository:** https://github.com/openstatsware
- **Official website**: https://openstatsware.org

Awards, Honors, Recognitions

- **"SIG of the Year" award** at the PSI conference in Dublin, Ireland, in June 2026 (including contributed session at PSI conference 2027)



The Board of Directors would like to congratulate

OpenStatsWare

on receiving the

SIG of the Year Award 2026

In recognition of their outstanding contribution to the PSI community. Through extensive cross-company collaboration, the development of widely used open-source tools, and delivery of global workshops, they have made a significant and lasting impact. Their global reach, sustained impact, and strong community engagement set a new benchmark for PSI Special Interest Groups.

Congratulations on this achievement.

Outlook

- **Software engineering is a critical competence** in producing high-quality statistical software
- Developing open-source statistical software **maximizes benefit for the statistical community** by using collaboration **between subject matter expertise across organizations**
- The **establishment, dissemination and adoption** of best practices for software engineering of open-source software requires **more work**
- Better software engineering will improve the **efficiency, reliability and innovation within Biostatistics**

Thank you!

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References

- Ya Wang, Thomas Jaki, Laura Pascasio Harris, Elias Laurin Meyer, Wilmar Igl, Nan Chen (2026). CRAN Task View: Clinical Trial Design, Monitoring, Analysis and Reporting. Version 2026-09-02. URL: https://CRAN.R-project.org/view=ClinicalTrials.

- Brock K, Chen C, Ho S, et al. A Bayesian method for safety signal detection in ongoing blinded randomised controlled trials. *Pharmaceutical Statistics*. 2023; 22(2): 378-395. doi:10.1002/pst.2278

- **Packages & Code Repositories:**
  - Sabanes Bove D, Li L, Dedic J, Kelkhoff D, Kunzmann K, Lang B, Stock C, Wang Y, James D, Sidi J, Leibovitz D, Sjoberg D, Krieger N, Panagos A, Jones J (2026). mmrm: Mixed Models for Repeated Measures. R package version 0.3.18, https://openpharma.github.io/mmrm/.
  - https://openpharma.github.io/brms.mmrm/
  - https://github.com/hta-pharma/
  - https://openpharma.github.io/SafetySignalDetection.jl/