openstatsware:
Let's improve open-source statistical software together!

Alessandro Gasparini (Red Door Analytics), on behalf of `openstatsware.org`

Introduction

`openstatsware` was founded in August 2022 as a scientific working group of the **ASA Biopharmaceutical Section**.

In March 2024, `openstatsware` became an official **EFSPI/PSI SIG**.

It currently includes **more than 65 members** from over 35 organizations.

Objectives

- **Primary:**

  Engineer R packages that implement important statistical methods

  - to fill in gaps in the open-source statistical software landscape
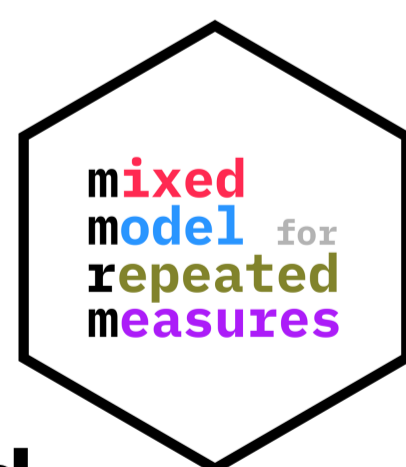 - focusing on what is needed for biopharmaceutical applications

- **Secondary:**

  Develop and disseminate best practices for engineering high-quality open-source statistical software

  - by actively doing the statistical engineering work together, we align on best practices and can communicate these to others

R Package {mmrm}

- **First R package** project of `openstatsware`

- **Mixed Models for Repeated Measures (MMRM)**
  Note: misnomer, it just has fixed effects + a structured covariance matrix ☺

- Was needed to **match results of SAS** for degrees of freedom adjustments (Satterthwaite, Kenward-Roger)

- Available on CRAN

R Package {brms.mmrm}

- Leverages `{brms}` to perform Bayesian inference in MMRM

- Supports a simplified interface to reduce difficulty and align with best practices for pharma use

- Package has been validated using simulation-based calibration and comparisons against the frequentist `{mmrm}` package on two example datasets

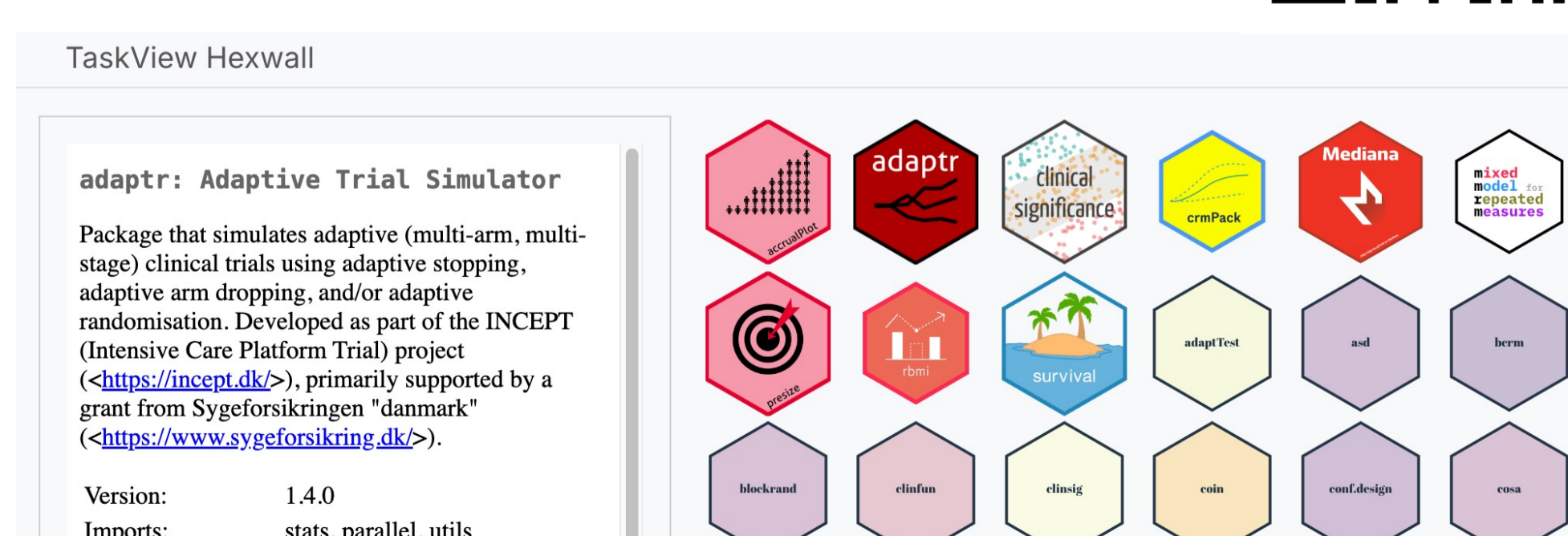- Available on CRAN

R Package {maicplus}

- Facilitates performing matching adjusted indirect comparison (MAIC) analysis where the endpoint of interest is either time-to-event (e.g. overall survival) or binary (e.g. objective tumour response)

- Supports HTA dossier submission across various countries

- Under development on GitHub

{SafetySignalDetection.jl}

- **First Julia package** project of `openstatsware`

- Implements **Bayesian safety signal detection** as proposed by Brock et al. (2023) using the Turing.jl framework

- Available on the central Julia registry

Clinical Trials Task View

- Developed a new hex wall view of the Clinical Trials CRAN task view

TaskView Hexwall

adaptr: Adaptive Trial Simulator

Package that simulates adaptive (multi-arm, multi-stage) clinical trials using adaptive stopping, adaptive arm dropping, and/or adaptive randomisation. Developed as part of the INCEPT (Intensive Care Platform Trial) project (<https://incept.dk/>), primarily supported by a grant from Sygeforsikringen "danmark" (<https://www.sygeforsikring.dk/>)

Version: 1.4.0
Imports: stats, parallel, utils

Best practices

- We want to spread the word about:
  User interface design
  Code readability
  Unit and integration tests
  Documentation
  Version control
  Reproducibility
  Maintainability
  Etc.

- Workshop **"Good Software Engineering Practice for R Packages"** is on a world tour: 7 events in 2023 and 2024 (Basel, Shanghai, San José, Rockville, Montreal, Zurich, Salzburg)

- `openstatsguide`, a short and concise set of Minimum Viable Good Practices

Lessons Learned

- Important to **go public as soon as possible** – don't wait for the product to be finished, you want to involve people you don't even know yet!

- Building software **together works better than alone** – different developer perspectives optimize the user experience

- Lowering the entry hurdle using **developer calls** is important, including Slack channels for communication

Long Term Perspective

- Software engineering is a **critical competence** in producing high-quality statistical software

- A lot of work needs to be done regarding the **establishment**, **dissemination** and **adoption** of best practices for engineering high quality open-source software

- Improving the way software engineering is done **will help improve** the **efficiency**, **reliability** and **innovation** within Biostatistics

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