



Joining the pharmaverse revolution

PHUSE EU SDE @Basel, Sept 2025

Fanny Gautier (Cytel), Ilse Augustyns (J&J), Stefan Pascal Thoma (Roche)



Introduction

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- Pharmaverse is a PHUSE WG: working to promote collaborative development of curated open source solutions for clinical reporting usage in pharma
- Covers >40 packages with ~400 contributors and >1,500 community members
- Today we will share our experiences contributing as members of this community



Fanny Gautier

Principal Statistical Programmer, Cytel

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From SAS to Open Source

- SAS background in pharma industry
- Self-learning R
- First exposure to GitHub and using R in daily work



Fanny Gautier (cont.)

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Getting Started with {admiral}

- Joined {admiral} dev team in early 2024
- Warm welcome, strong onboarding process (incl. dummy issue)
- Supportive and collaborative team atmosphere
- You are never alone, and you can't really break anything!

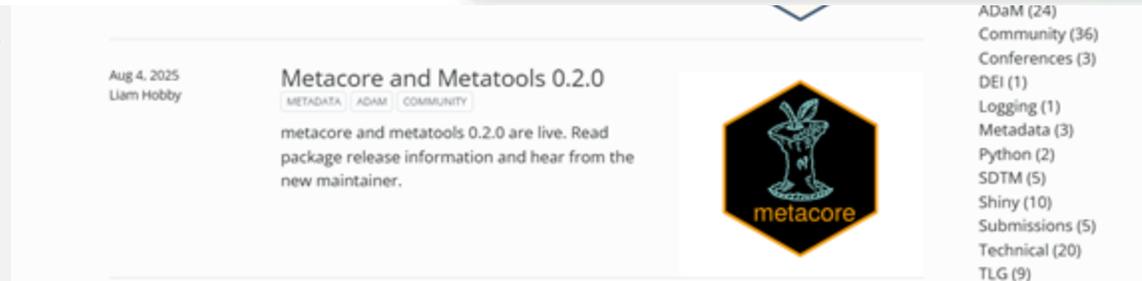
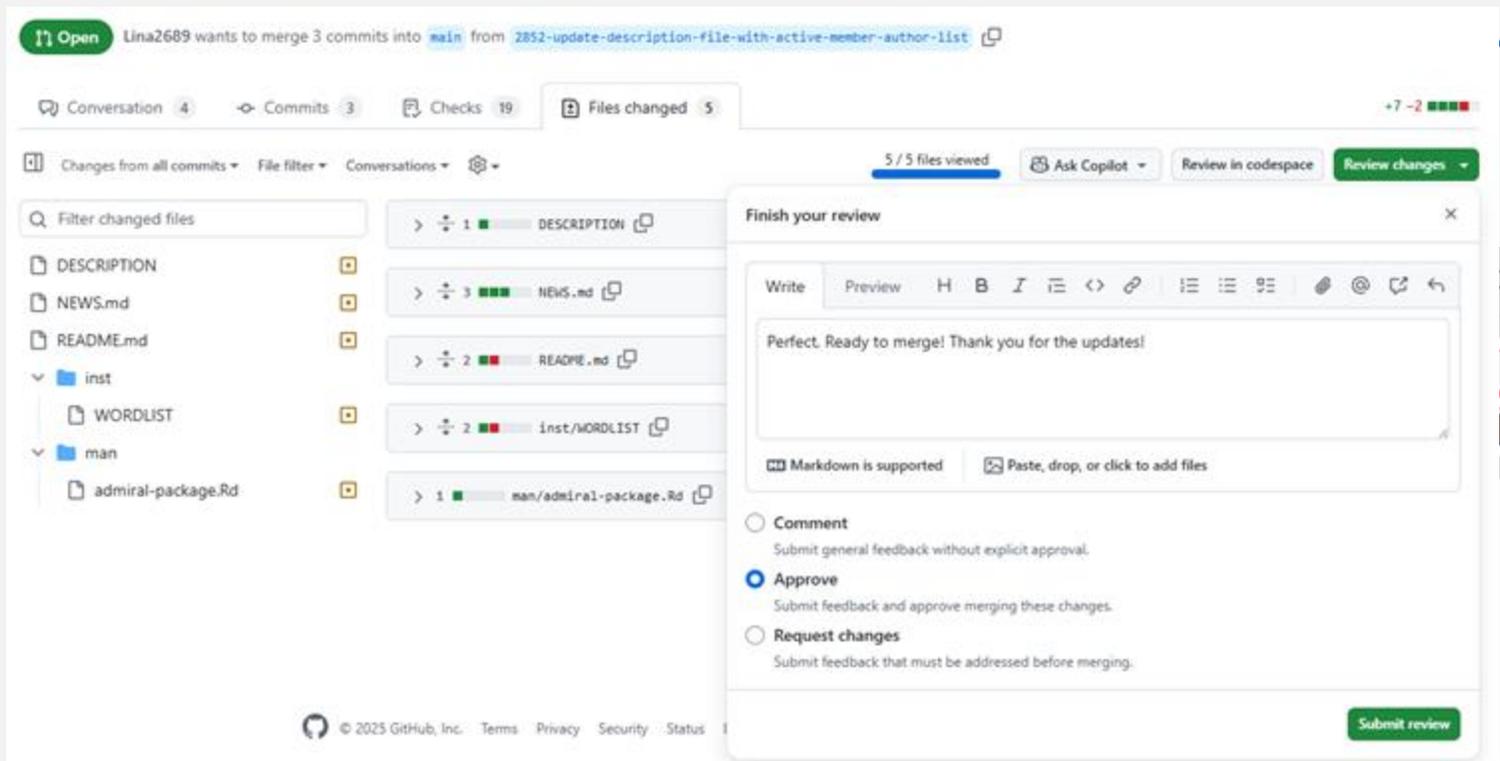




Fanny Gautier

Ways to Contribute

- Not just coding:
 - Report bugs
 - Review PRs
 - Write documentation & vignettes
 - Create templates or blog posts
 - Join community meetings, etc.
- Every skill is valuable: therapeutic area knowledge, CDISC, R, writing, testing, perseverance





Fanny Gautier (cont.)

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My Contributions & Impact

- Active contributor to {admiral}, co-developer & maintainer of {admiralpeds}
- Helped build {admiralneuro}, blog, pharmaverse/examples, workshops, and other pharmaverse packages
- Open source = clear, reusable code that saves time & boosts quality
- No need to reinvent the wheel!



Fanny Gautier (cont.)

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What Open Source Gave Me

- Strong R programming skills & enhanced CDISC expertise
- Deep understanding of R packages & co-development processes
- Opportunities to act as SME, co-chair workshops (RinPharma 2024), present at conferences (PHUSE, Public Hospital)
- Grew beyond comfort zone and loved every step!



Fanny Gautier (cont.)



By becoming an active contributor, you also become a stronger and more confident user





Ilse Augustyns

Principal Technical Lead, JJ

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Started as Stat/ Stat Programmer in Pharma@JJ in 1998

- TA and Study Level support

2021: Moved into new role

- support and innovation for Statistical Programming group

SAS has been THE system in pharma industry for Statistical Programming

- Every company has its own reporting system build

Last decade:

- Shift towards newer platforms: R, Shiny, Python, Julia
- more collaboration within industry: PHUSE and pharmaverse



Ilse Augustyns – R for TLF generation

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SAS to R switch @JJ for TLF

- Started in 2021
- Encourage programmers to learn R and start using it
- Mainly for QC, not yet production

Conversion of SAS toolkit into R toolkit

- 2021-2023: JJ package: {tidytlg} (also on pharmaverse)
 - Basic frequency and descriptive statistics
 - Very limited efficacy
 - Static tables only
- 2022: start Evaluation of Roche NEST framework
 - Not limited to descriptive methods only
 - Interactive component {teal}
 - Gap analysis for usage @ JJ



NEST framework

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NEST (Nested Evidence Structure Tables) is an open-source initiative led by Roche to standardize and streamline clinical trial reporting for regulatory submissions.

- Part of **Pharmaverse** packages in the **TLGs** category.
- <https://pharmaverse.org/e2eclinical/tlg/>

CORE framework

{rtables}: enables the creation of complex, hierarchical tables using a grammar-like syntax.

- Main **Building blocks** for table creation
- It supports **flexible row/column splitting, multi-level tabulations, and contextual summaries**
- **advanced customization and layout control**
- Not specific to any specific company's reporting style

Business logic framework

{tern}: complements rtables by providing **statistical analysis functions**.

- tailored for **clinical trial data**
- Specific to Roche's 'flavor' of the various table and listing outputs which are included in a clinical filing
- More 'opinionated' and did not fully meet our company needs.

Instead of rejecting the framework in light of the identified gaps, we have embraced the framework and joined collaboration with Roche to contribute



JJ/Roche collaboration on NEST

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JJ Contributed to {rtables}:

- True-type font support (non-monospace font, word wrapping & pagination)
- Higher order column counts
- SAS-like rounding support (nearest-value)

{junco}: JJ business logic features not covered in {tern}

- Production-ready RTF export
- Statistical presentations subtly different from tern
- Alternate approach for risk difference columns
- Utilities for spanning column headers

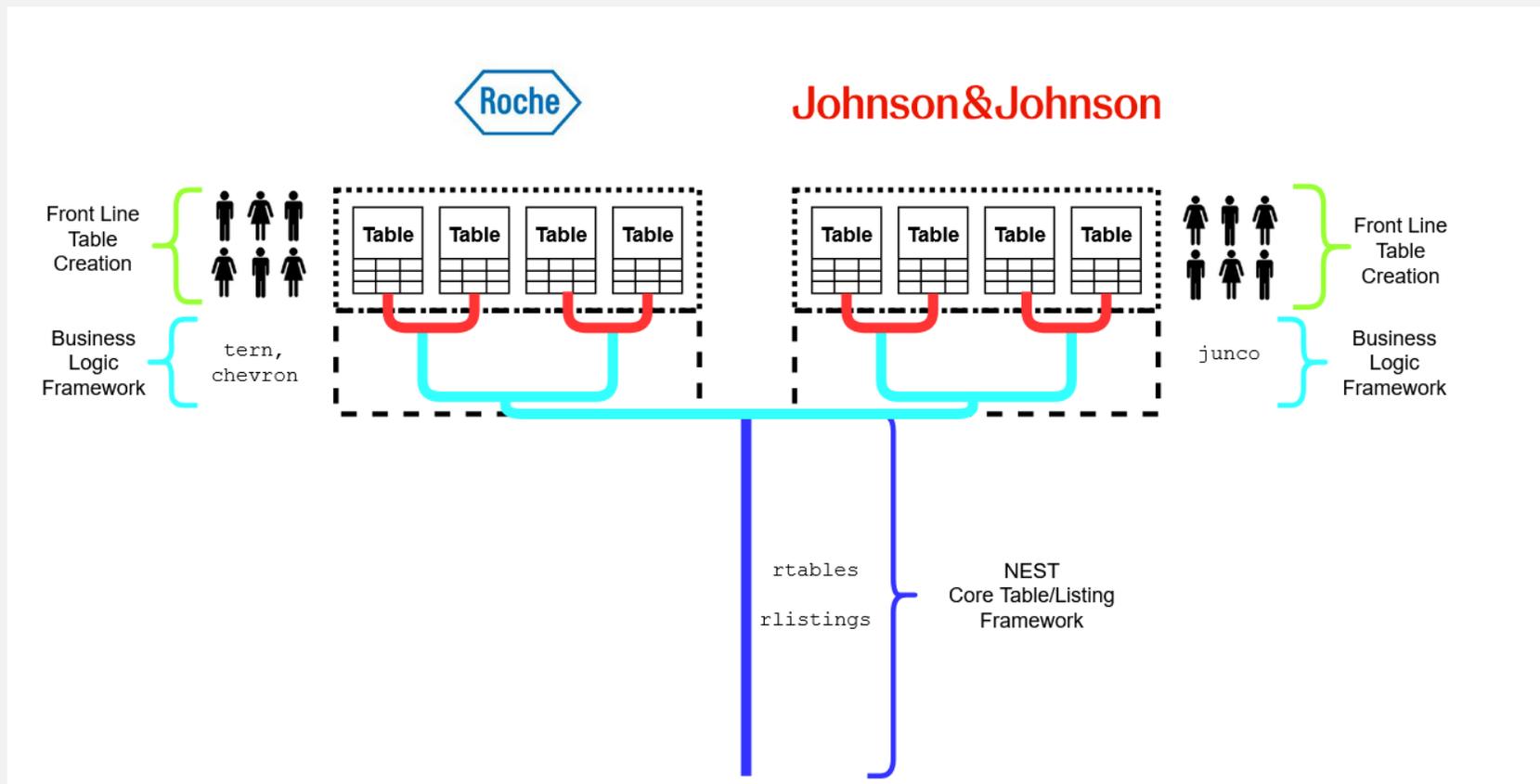
{tern}:

- Extend statistical functions with new statistics to support JJ shells
- Extra exported functions upon JJ requests for usage in junco



Status NEST @ JJ

- Nov 2024: Initial rollout of NEST framework + JJ template shell scripts (pre-junco package release)
- October 2025: rollout of extended NEST framework (including {junco}) + JJ template scripts/catalog





Open source benefits

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Strategic Collaboration

- contributing to shared frameworks, organizations **align** with **industry standards** and **reduce duplication of effort**
- more consistency and interoperable tools across companies
- collaboration on analytical tools benefits everyone
- shared open source efforts can accelerate innovation while reducing costs

Community-Driven Quality

- contributions from a diverse group of experts lead to more **robust, well-tested code**
- **Broader testing:** Diverse use cases identify edge cases and bugs more effectively
- benefit from **peer reviews, issue tracking, and continuous integration**

Transparency and Trust

- promotes **transparency** in **methodologies** and **implementations**
- This is especially valuable in **regulated industries** like healthcare and pharma

Shared maintenance burden

- Multiple companies contribute to maintaining core infrastructure



Open source benefits (cont'd)



Professional Growth

- Contributors gain **visibility**, expand their **technical skills**, and build reputations within the community
- Gained deeper understanding in package development process:
 - package documentation
 - Testing & validation: unit tests, code coverage, integration tests
 - Continuous integration and deployment: automated testing, style checking, documentation building (keep documentation in sync with code)
 - Version control and collaboration: Git, issue tracking

Other

- Inclusive: anyone can contribute by feedback, suggestions, bug reports, submitting a PR
- Young talent: university grads and professionals are familiar with OS way of working - Github, R, software development



Challenges

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- **Timing:** aligning external R package releases to meet internal roadmaps : container release twice a year to quarterly releases
- **Multi-package framework:** what to cover in which package, e.g. {rtables}/{tern} vs company specific {junco}
 - e.g. initial version of SAS rounding was kept in {junco}, now it is addressed in {rtables}
- Ensure **no breaking changes** when introducing new features
- **Package dependencies:** updates to {tern}/{rtables} code changes could lead to breaking internal code bases (like internal TLG catalogs)
- Following **other companies process** for PR, and become familiar with all components in workflow



Mitigations

- **Communication**
- Relationship & trust
- transparency regarding roadmaps
- Identification sharing of gaps, highest critical needs
- Testing!

What's next

- Incorporate testing for internal JJ catalog in scda.test (Roche workflow)
- **Maintain the collaborative spirit!**

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Stefan Pascal Thoma – Background

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- Statistical programmer at Roche for 3 years
- R and statistics background
- In the industry **because of** Roche's investment in open source



Stefan Pascal Thoma – Open Source Contributions

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- Started with limited package development experience
- (Part-time) Developer on {admiral}
- Started the pharmaverse blog with Ben Straub and Edoardo Mancini
- Contribute to other pharmaverse packages in various ways



Stefan Pasca

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StefanThoma commented on Mar 19

Member Author ...

hi @bundfussr
I have created one new internal function for the assertions.
I did leave out the assertion for the variable in the dataset, I think it would have overcomplicated it.

@bms63 I figured out the complexity stuff: The original functions (derive_vars_dt and ...dtm) were linted cyclo-complexity ignored 😊
The additional assertion function I created on its own had cyclo-complexity of 29, so I just cyclo-complexity ignored that one, therefore reducing the number of ignored functions.

Let me know what you all think about the current state. Once merged in, I can take care of the bug in the other issue.

Closes #2654 derive_vars_dt error messaging #2672

Merged

manciniedoardo merged 110 commits into `main` from `2654-documentation-derive_vars_dt` on May 27

Conversation 166

Commits 110

Checks 19

Files changed 37



StefanThoma commented on Mar 4 • edited

Member ...

oh no - does this update increase the check a little more

```

1  linters: linters_with_de
2  line_length_linter(1
3  object_usage_linter=
4  cyclocomp_linter(com
5  indentation_linter=N

```

- update get_partiatetime to also do dates ✓ 13e9b21
- get_dt_dtm_range returns range ✓ 1e0cf88
- remove is_datetime argument ✓ 2e65f39
- inherit params for get_imputation_targets ✓ 7d2feff
- add function to check ✓ e9a323d
- minor fix ✓ c83f6a4
- removed is_datetime from all functions ✓ 2b27684
- rename impute_values to impute_date_time ✓ 538ca75

StefanThoma commented on May 23

Member Author ...

Hi @bundfussr



Stefan Pascal Thoma - Learnings

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- Set aside enough time,
- One issue at a time
- Learning experience vs. being super efficient



Stefan Pascal Thoma – Issues as contributions

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- Please report bugs / typos / errors and feature requests on github
- 3 levels of feature requests
 - a. Specific and contextual. Include motivation. Imagine talking to ChatGPT.
 - b. Include (working) proof of concept code with input and expected output
 - c. Offer to implement the feature in the package



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How could you get involved?

- Visit pharmaverse.org
- See FAQ section of the homepage:

How can I get involved?

Firstly, join our community on Slack using this [link](#). We are always looking for new collaborators to join us in helping achieve our vision - visit our [Contribute](#) section of the site for all options.

- Example options of contributing:

- Raise feedback via Issues for areas where you find potential package enhancements or bugs
- For those packages with an open contribution model, develop new functionality and make pull requests to make your code available for re-use
- For new pharmaverse package collaborations, volunteer for user testing to help the development team build robust solutions

