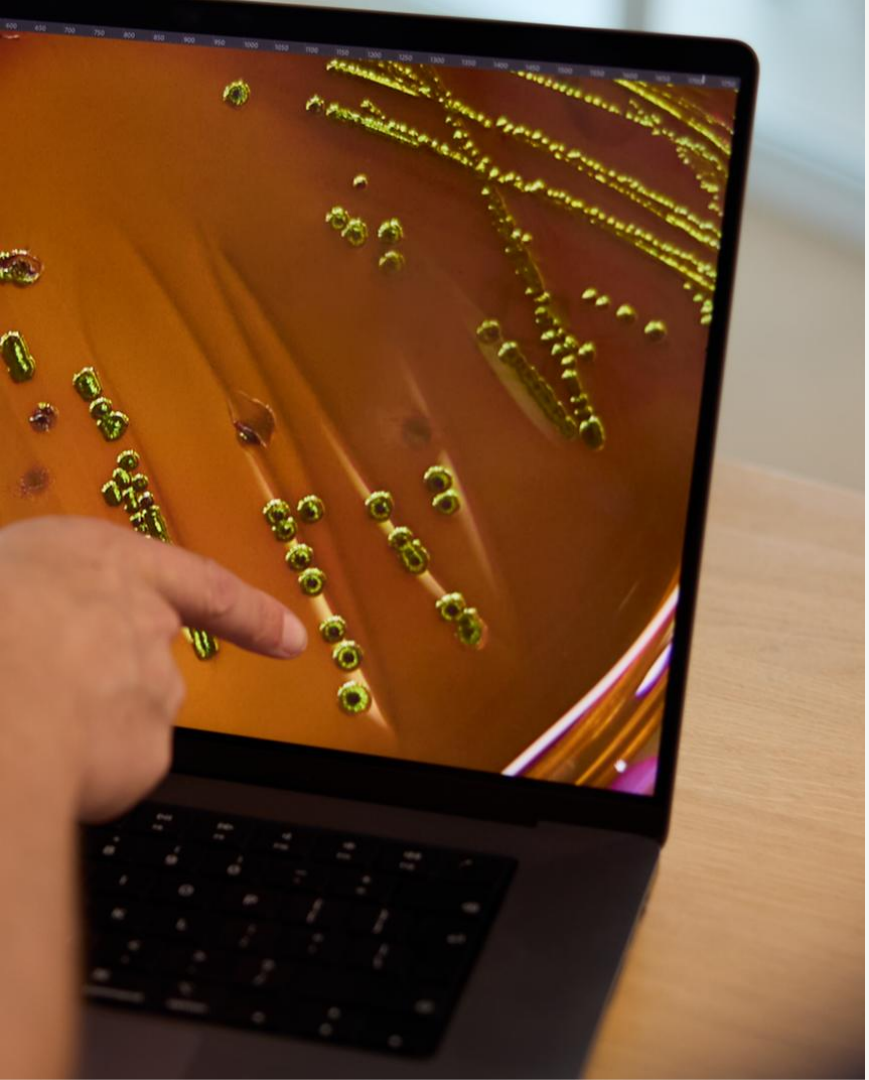

Scaling Statistical Innovation with Open Source Collaborations

Presentation subtitle

Isaac Gravestock,
Statistical Engineering (Methods, Collaboration and Outreach)
F. Hoffmann-La Roche

10.06.2025 | Public

“It is a truth universally acknowledged, that a pharmaceutical industry statistician in possession of a good statistical method, must be in want of a user friendly software implementation.”

- Jane Austin (1813)

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Why Innovation?

- Clinical development is becoming more complex
- Pressure to improve success rates
- Pressure to go faster and reduce resources
- AI

Why Software?

Subtitle goes here but is not mandatory

- Pencil and paper not enough in 2025
- Each statistician programming from scratch is not efficient
- Ready made tools allow easy evaluation of new methods
  - Build understanding how and when to apply

Phases of Methodological Research in Biostatistics

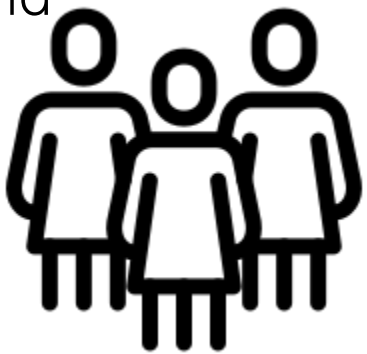
- Heinze et al propose 4 phases of evidence for methods:
  1. Establish theoretical validity
  2. Show the method could be used with caution
  3. Show settings when the method works safely and performs well
  4. Know when competing methods are preferred, know pitfalls and have diagnostics

Heinze et al. (2024). Phases of methodological research in biostatistics–
Building the evidence base for new methods.
Biometrical Journal, 66, 2200222. https://doi.org/10.1002/bimj.202200222

Why Collaborate?

Subtitle goes here but is not mandatory

- There are no secret statistical methods in late stage
- Need to build confidence and understanding about when methods are suitable
- Work together to make sure that the methods and software implementations are fit for purpose



Why Open Source?

Subtitle goes here but is not mandatory

- Simplifies collaboration and ownership
- Companies can adapt to their own needs
- Implementation is open for review and critique
  - Corrections and bug fixes

Growing Landscape

- Lots of growth in Open Source in Pharma!
- Pharmaverse for analysis and reporting tools
- R Consortium sponsoring projects
  - R submission pilots for FDA
- CAMIS: comparing software implementations

Some Successes

Reference-based Multiple Imputation: rbmi

- 2022 PSI/RSS Statistical Excellence award winner
- Software establishing use of this method in pivotal studies
- Further development on-going with other pharma

github.com/insightsengineering/rbmi

IMPALA Consortium for Quality

- Industry-wide consortium to improve methods in Quality
- Work packages to develop “advanced analytics” and software
- Materials to help commercialisation and adoption of innovation

impala-consortium.org

rpact

- Comprehensive package for trial design and analysis
  - Especially group sequential design
- Open source and available for free
- Commercial support available from **RPACT**
- +10 pharma companies and CROs contribute to further development

rpact.org

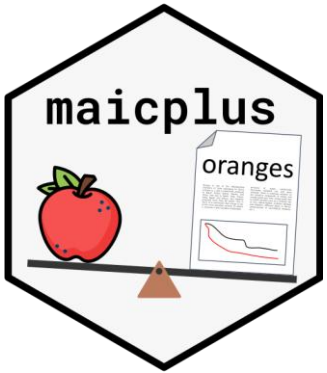
R Validation Hub

- Enabling validation of open source software, so that companies can adopt innovative solutions
- Solving a common problem for all companies
- Working group of the R Consortium

pharmar.org

Matching Adjusted Indirect Treatment Comparisons: maicplus

- Started development between 2 companies to merge their implementation of MAIC methods
- Established Health Technology Assessment workstream under OpenStatsWare
- Now with contributors from 5 companies
  - Bug reports from many more!



Bayesian Dynamic Borrowing (BDB)

- GSK won 2024 Statistical Excellence in the Pharmaceutical Industry Award for successful use of BDB
- Lots of academic work going on
- Various independent software projects:
  - RBesT, hdbayes, beastt, psborrow2, …
- Could there be a common project?

Doing now what patients need next