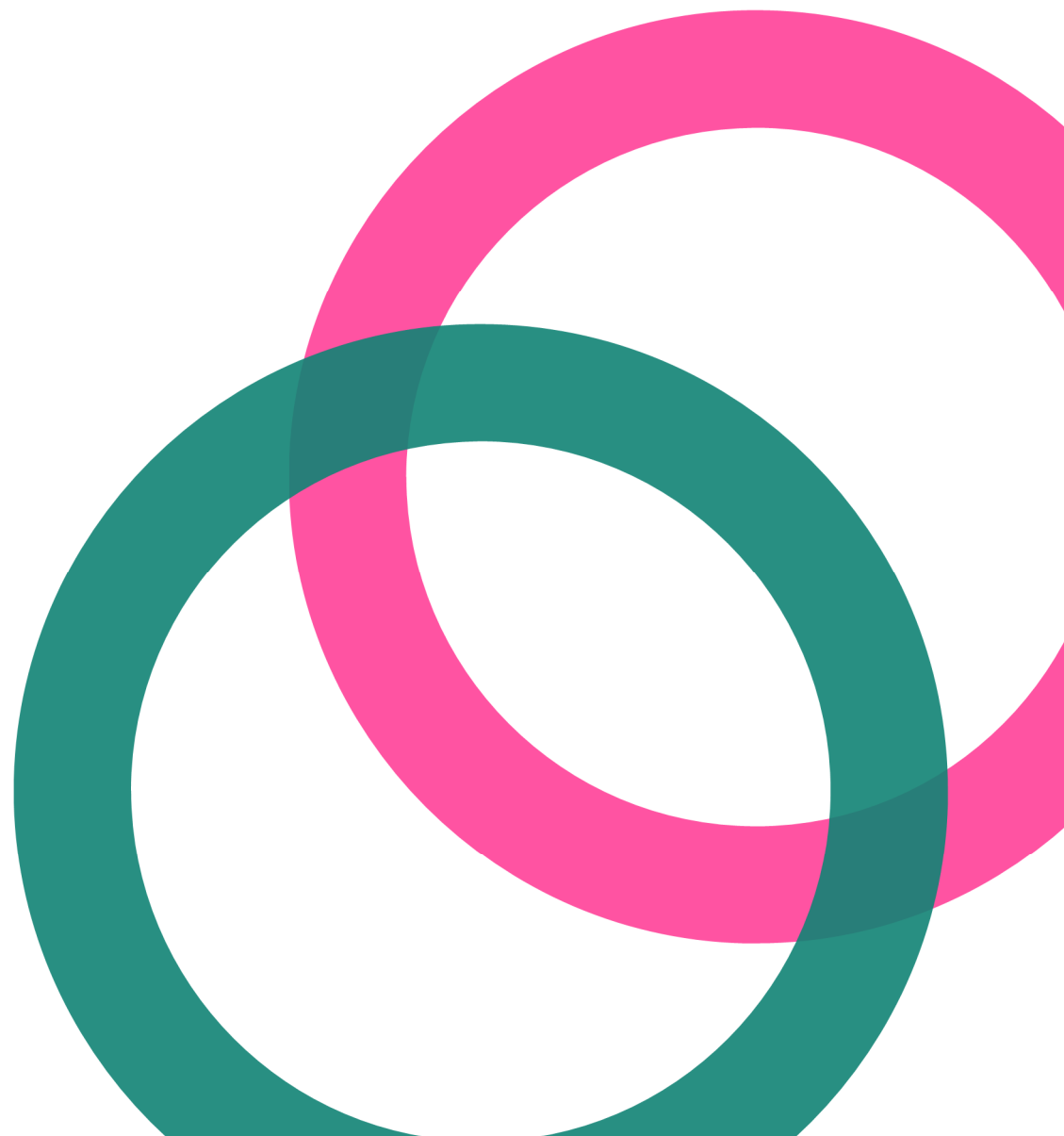




## CDISC Hackathon: "admiral" - Insights

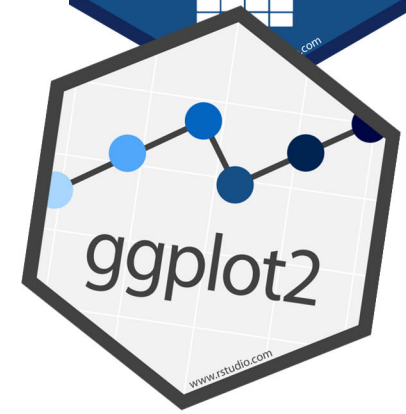
14 – March 2023

Andrea Weber



# TOPICS

- Some Basics of R and R packages
- ADMIRAL (ADaM in R Asset Library)
- Hackathon
- And the authorities ??





# Some Basics of R and R packages

## Some Basics of R and R packages

### What is R

- Programming language
- Open source
- Free software
- Initially for statistics and graphs
- In the meanwhile, further developed for complex data science purposes
- Used at Academics



# Some Basics of R and R packages

## R Packages

- Toolboxes of R functions
- Each toolbox is for a specific purpose
- Examples are:
  - dplyr           -> data manipulation
  - ggplot2       -> graphics
  - readr          -> read data in rectangle format (csv, tsv)
  - haven          -> read in and write out xpt files.



## Some Basics of R and R packages

### Packages examples cont.

- stringr -> string manipulation
- metacore -> objects of metadata
- metatools -> enable use of metacore objects (apply formats, attributes etc.)
- xportr -> export xpt in submission ready fashion inclusive checks.
- admiral -> ADaM datasets
- .... many more



# Some Basics of R and R packages

## Tidyverse

- Group of R packages for data analysis.
- Owned by Posit / Rstudio
- Common design, grammar and data structure
- Packages of general functions
- Examples of packages included: dplyr, ggplot2, readr, haven, stringr etc.





## Some Basics

### Pharmaverse

- Brings all pharma related packages together
- Network of industry individuals working with and developing of R-packages, guided by the pharmaverse council
- Agreement of packages
- Identification of missing tools
- Ensure industry standard.



## Some Basics of R and R packages

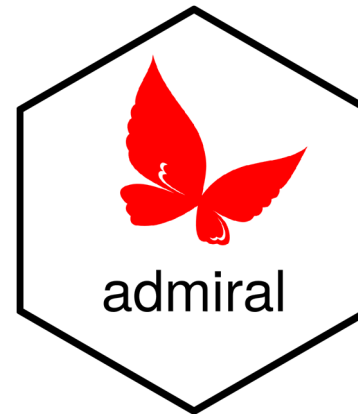
### Core principle / Vision of Pharmaverse

- Programming standards across industry
  - Consistent programming across industry
  - Robust functions since tested by a broader user community
- Collaboration across industry
  - Companies benefit from existing functions
  - Contributors can add new functions for public use



# ADMIRAL

ADaM in R Asset Library



# ADMIRAL

- Package of functions specific to creation of ADaM
- Uses function of other packages.
- Common standards for ADSL, BDS, OCCDS, TTE
- Development phase (current version: 0.10.0)
- New releases last month of each quarter



# ADMIRAL

## - 3 planned types of packages

- Core package
  - Core functions to create ADaM
- Therapeutic Area package
  - Functions specific to a therapeutic area
  - As of now: Oncology, Vaccine and Ophthalmology
- Company package
  - Functions and plug-ins specific to a company (e.g., admiralroche, admiralgsk)



# ADMIRAL

## Contains derivation of



– Age in years

-> derive\_var\_age\_years

– Age groups

-> derive\_agegr\_fda, derive\_agegr\_ema

– Treatment start and end

-> derive\_var\_trtsdtm, derive\_var\_trtedtm

– Treatment duration

-> derive\_var\_trtdurd

– Baseline flag

-> derived\_extreme\_flag

– Baseline

-> derive\_var\_base, derive\_var\_basec

– BMI, BSA

-> derive\_param\_bmi / compute\_bmi

-> derive\_param\_bsa / compute\_bsa

.... many more

## Further functions



- Timing -> convert\_dtc\_to\_dtm, derive\_var\_day
- User and developer utilities -> convert\_blanks\_to\_na, extract\_unit
- ADSL specific -> derive\_var\_dthcaus, derive\_vars\_period
- OCCDS specific -> derive\_var\_trtemfl, derive\_vars\_atc
- BDS specific -> derive\_var\_chg, derive\_var\_pchg
- TTE specific -> derive\_param\_tte

# ADMIRAL

More information

[ADaM in R Asset Library • admiral \(pharmaverse.github.io\)](https://pharmaverse.github.io/admiral/)







# Hackathon

# HACKATHON

## Objectives

- Opportunity to create ADAM by using ADMIRAL
- Transform SDTM to ADAM as we do in day-to-day work
- Functions ‘tested’ and used by broader user community
- Feedback on issue (example xportr issues with applying formats from metacore)

# HACKATHON

## Conduct

- 1 - 28 February
- 3 hours R introduction course for SAS programmers
- 8 ADaMs (ADSL, ADVS, ADDAS, ADAE, ADTTE, ADLBH, ADLBC, ADLBHY)
- Specs, SAP, aCRF provided by organizer
- Upload to Shiny App for comparison against expectations
- Scores depending on how best variables matches
- Slack as communication platform to ask questions

# HACKATHON

## My Experience

- R knowledge required (at least the functions of the base packages).
- Cheat sheet with SAS functions and their corresponding R functions only covered basics but less than I had needed
- Possibility to play around and thus learning by doing
- Learned a lot about R
- Feel that I am in still at the very beginning of an interesting journey



**And the authorities ??**

## And the authorities ??

### FDA

- Agnostic in terms of statistical software  
<https://fda.report/media/109552/Statistical-Software-Clarifying-Statement-PDF.pdf>
- As per file format specification multiple languages are accepted  
<https://www.fda.gov/media/85816/download>)
- FDA representative involved in RConsortium submission work group  
<https://github.com/RConsortium/submissions-wg>  
<https://www.r-consortium.org/using-r-in-regulatory-review>
- Best to speak to the reviewer ahead

## And the authorities ??

### PMDA

- Generally, no restrictions on programming language (statement by PMDA provided during a discussion done by the RConsortium submission work group "*At PMDA, there are no special restriction about analysis software for submission used by the applicant*")
- Best to speak to the reviewer ahead
- More info reg. R-Submission pilots in RConsortium submission work group

[GitHub - RConsortium/submissions-wg: R Submissions Working Group](https://github.com/RConsortium/submissions-wg)

# ICON



[ICONplc.com](https://www.ICONplc.com)

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