Overview of R \{admiral\}

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Today’s Agenda

1. What is {admiral}
2. Feature of {admiral}
3. {admiral} family
4. {admiral} manifest
5. Questions about {admiral}
6. Example of coding
What is {admiral}

• {admiral} is one of the R package of pharmaverse.

https://pharmaverse.org/
• {admiral} is part of the pharmaverse and that is supported by PHUSE.

• The **PHUSE mission** is stated as: “Sharing ideas, tools and standards around data, statistical and reporting technologies to advance the future of life sciences.” In support of this mission, in 2023, PHUSE pledged to support the **mission of pharmaverse** to “bring together a collection of pharmaceutical industry representatives to agree on a curated and opinionated subset of open-source software packages and codebases, which would be based on the R language and those that we believe are the most suitable for the industry to adopt in order to deliver the clinical data pipeline.” PHUSE is enabling the development of pharmaverse by enabling communication and development, both internally to individual packages and externally to the broader community.
What is \{admiral\}: ADaM in R Asset Library

**History:** In 2020, Thomas Neitmann (currently at Denali Therapeutics, then at Roche) and Michael Rimler (GSK) discovered that both were working with ADaM in R, so Thomas Neitmann, Ross Farrugia (Roche) and Michael Rimler (GSK) saw an opportunity there and GSK started their partnership with Roche to build and release {admiral package}.

**Purpose:** To provide an open source, modularized toolbox that enables the pharmaceutical programming community to develop ADaM datasets in R.

**Installation:** The package is available from [CRAN](https://pharmaverse.github.io/admiral/cran-release/index.html) (Comprehensive R Archive Network) and can be installed by running: `install.packages("admiral")`.

Features of {admiral}

- {admiral}’s Modular approach
  - Not one large function: e.g., create_advs()

```r
create_advs(
  sdtm_name = vs,
  param_01 = lbtest,
  param_02 = ,
  ...
  param_99 =
)
```

```r
advs %>%
  derive_vars_a() %>%
  derive_vars_b() %>%
  derive_param() %>%
  study_vars() %>%
  project_vars() %>%
)```

R/Pharma 2022 Workshops: https://www.youtube.com/watch?v=9eod8MLF5ys&list=PLMtxz1fUYA5AWYQHB5mZAs-yamNJ5Tm_8&index=3
{admiral} family

**Type: Core**

**Copyright holder:** Roche, GSK

**Therapeutic: Oncology**

**Copyright holder:** Roche, GSK, Amgen, Bristol Myers Squibb

**Therapeutic: Ophthalmology**

**Copyright holder:** Roche, Novartis

**Therapeutic: Vaccine**

**Copyright holder:** Pfizer, GSK, J&J

https://pharmaverse.org/e2eclinical/adam/

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{admiral} manifest

**Usability**
All admiral functions should be easy to use.

  e.g., Documentation is an absolute priority. Each function reference page should cover appropriate information.

**Findability**
All admiral functions are easily findable.

  e.g., Use consistent naming conventions across all our functions.

**Simplicity**
All admiral functions have a clear purpose.

  e.g., Not to ever design single functions that could achieve numerous very different derivations.

**Readability**
All admiral functions follow the Programming Strategy.

  e.g., Modularity is a focus - not try to achieve too many steps in one, all code has to be well commented.

Questions about \{admiral\} -1

• **Question 1:**
  • Would \{admiral\} create a whole ADaM dataset? Will \{admiral\} provide ADaM IG CDISC compliant datasets?

• **Answer 1:**
  • \{admiral\} is meant as a toolbox to enable Data Scientists to build ADaMs according to their varying analysis needs.
  • \{admiral\} is not meant as a “click a button, out comes your ADaM” tool.
  • On the \{admiral\} webpage, example scripts are provided which can be used as a starting point to create an ADaM (see at the end of a vignette).
  • Guidance will be provided for ADSL, BDS and OCCDS ADaM structure including template scripts.
  • Although \{admiral\} follows CDISC standards it does not claim that the dataset resulting from calling \{admiral\} functions is ADaM compliant. This has to be ensured by the user.

https://pharmaverse.github.io/admiral/cran-release/articles/faq.html
Questions about \{admiral\} -2

- **Question 2:**
  - Is the \{admiral\} package validated?

- **Answer 2:**
  - All functions are reviewed and tested (see What will be provided around function testing?) to ensure that they work as described in the documentation.
  - Any code changes done in admiral will trigger a run of all these tests (600+). Link to the test folder: https://github.com/pharmaverse/admiral/tree/main/tests/testthat
  - The testing the admiral team will do for each function does **not replace the QC and validation process at each company**.
  - During 2021, a limited release testing was conducted with 18 other companies (and >50 individuals) in order to assess compatibility of the admiral toolkit with different company standards implementations and to test the usability of the functions, e.g., clarity, reliability, robustness, and flexibility.

https://pharmaverse.github.io/admiral/cran-release/articles/faq.html
Questions about {admiral} -3

• Question 3:
  • Can users organize {admiral} paid or non-paid training? Or Non-copyright holders can have a presentation about {admiral}?

• Answer 3:
  • Apache License is applied.
    • The Apache License is a free and open source software license written by the Apache Software Foundation (ASF) that is currently in its third iteration. It allows software and projects to be freely used, modified, or redistributed under the terms of the license for personal, commercial, or company purposes without concern for royalties.
  • Anyone can organize trainings on admiral.
  • Non-copyright holders can present on admiral – hopefully the content and delivery would do admiral justice.

https://pharmaverse.github.io/admiral/v0.12.2/LICENSE.html
Example of Coding
# Load packages
# The “admiral” package also leverages the “pharmaversesdtm” package for example SDTM datasets which are from the CDISC Pilot Study.
library(dplyr)
library(lubridate)
library(admiral)
library(pharmaversesdtm)

# Read in SDTM datasets
data("dm")
data("ds")
data("ex")
# Turn SAS blank strings into proper R NAs.
dm <- convert_blanks_to_na(dm)
ds <- convert_blanks_to_na(ds)
ex <- convert_blanks_to_na(ex)

# Derive treatment variables (TRT0xP, TRT0xA)
adsl <- dm %>%
  mutate(TRT01P = ARM, TRT01A = ACTARM)
# Impute time of exposure dates (creates numeric datetime and time imputation flag variables).

# Impute missing time to be 23:59:59 using time_imputation = "last".

```r
ex_ext <- ex %>%
  derive_vars_dtm( dtc = EXSTDTC,              
                   new_vars_prefix = "EXST" ) %>%
  derive_vars_dtm( dtc = EXENDTC,              
                   new_vars_prefix = "EXEN",    
                   time_imputation = "last"  )
```

# Derive variables for first/last treatment date and time imputation flags.

```r
adsl <- adsl %>%
  derive_vars_merged( dataset_add = ex_ext,
                      filter_add = !is.na(EXSTDTM),
                      new_vars = exprs(TRTSDTM = EXSTDTM, TRTSTMF = EXSTTMF),
                      order = exprs(EXSTDTM, EXSEQ),
                      mode = "first",
                      by_vars = exprs(STUDYID, USUBJID) ) %>%
  derive_vars_merged( dataset_add = ex_ext,
                      filter_add = !is.na(EXENDTM),
                      new_vars = exprs(TRTEDTM = EXENDTM, TRTETMF = EXENTMF),
                      order = exprs(EXENDTM, EXSEQ),
                      mode = "last",
                      by_vars = exprs(STUDYID, USUBJID) )
```

# Derive date variables (TRTSDT and TRTEDT) from date/time variables
# The datetime variables returned can be converted to dates using the derive_vars_dtm_to_dt() function.
adsl <- adsl %>%
    derive_vars_dtm_to_dt(source_vars = exprs(TRTSDTM, TRTEDTM))

# The function derive_var_trtdurd() can be used to calculate the Treatment duration (TRTDURD).
adsl <- adsl %>%
    derive_var_trtdurd()
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<th>FirstArm</th>
<th>Description of Planned Arm</th>
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Any Questions?