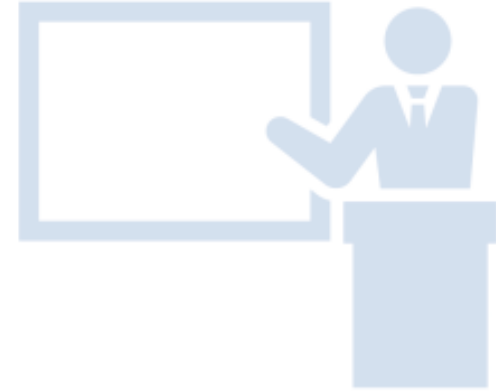


Lessons Learned from {admiralophtha} Development Activities

Yuki Matsunaga, Ph.D.
Novartis Pharma K.K.

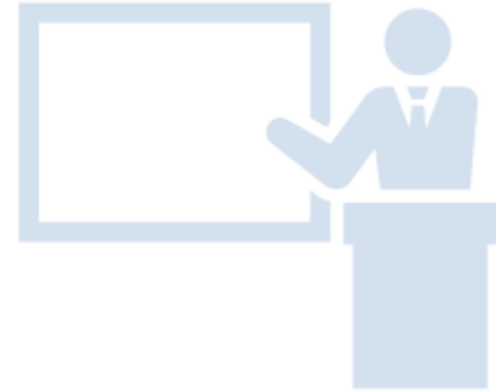
Agenda

- **General Background**
 - {admiral} / {admimralophtha}
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 - The Agile Method
 - Workflow
 - Github
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 - Went well / Challenges
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General background






{admiral}



admiral   OS Activity 0  Contributors 20





(ADaM In R Asset Library) - Modular framework to generate ADaM via R functions relying on community contributions




admiralonco   OS Activity 57  riskmetric 0.52  CRAN 0.5.0  Contributors 5

Oncology








admiralophtha   OS Activity 71  riskmetric 0.52  CRAN 0.3.0

 Contributors 4

Ophthalmology



admiralvaccine   OS Activity 71  riskmetric 0.57  CRAN 0.1.0

 Contributors 4

Vaccines RELEASE EXPECTED ~2023

General background



{admiral}



admiral   OS Activity **0** Contributors **20**



(ADaM In R Asset Library) - Modular framework to generate ADaM via R functions relying on community contributions



admiralonco   OS Activity **57** riskmetric **0.52** CRAN **0.5.0** Contributors **5**

Oncology





admiralophtha   OS Activity **71** riskmetric **0.52** CRAN **0.3.0**

Contributors **4**

Ophthalmology



admiralvaccine   OS Activity **71** riskmetric **0.57** CRAN **0.1.0**

Contributors **4**

Vaccines RELEASE EXPECTED ~2023

developed by a combined Roche and Novartis team

{admiralophtha}

{admiralophtha} v0.1.0 released



Edoardo Mancini

Statistical Programmer Analyst at Roche

公開日: 2023年3月15日

+ フォロー

I'm pleased to announce that following an intense few months of development efforts by a combined Roche and Novartis team, the first release of {admiralophtha} is now [live on CRAN](#). {admiralophtha} is an **R package extension for {admiral}**. While the latter aims to provide a toolset to construct ADaM datasets in R, **{admiralophtha} builds upon this to aid users in creating ophthalmology-specific datasets**.

For this first release, the team focused on delivering quality over quantity. We chose to develop tools to derive common ADaM variables such as STUDYEYE and AFEYE, along with utility functions to convert ETDRS scores to LogMAR units. Moreover a more complex function to make criterion flags for BCVA endpoints is also now available, and is an example of some of the more endpoint-specific tools that will come with future releases. We also made test data so that users can play around with the tools we built. Moreover, the package has a detailed [website](#) with vignettes showcasing the tools in action for common ophthalmology ADaMs such as ADOE, ADBCVA and ADVFQ.

Users will be able to install the package in their local R Studio by running `install.packages("admiralophtha")`. We encourage anyone with an interest in ADaM programming and ophthalmology to give {admiralophtha} a spin; gaining expertise with these tools will be especially valuable as we pivot towards more extensive use of R in the coming months and years.

Thanks to the development team for making this release possible!

Roche:

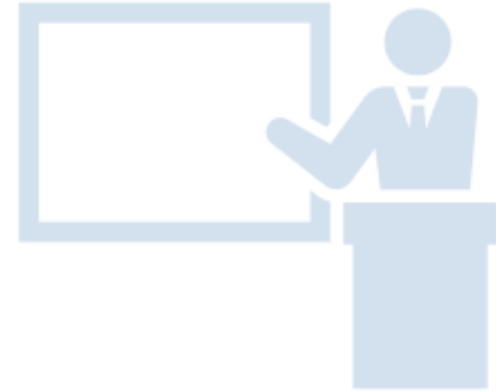
- [Edoardo Mancini](#) (lead)
- [William Holmes](#)
- [Jane Gao](#)
- [Rachel Linacre](#)
- [Gordon Miller](#)
- [Lucy Palmen](#)

Novartis:

- [Ritika Aggarwal](#)
- [Nandini R Thampi](#)
- [Yuki Matsunaga](#)

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The Characteristics - Agile Method vs Waterfall

Agile

- **Process:**
 - ✓ Fast iterative cycles
- **Time/ Resource/ Scope:**
 - ✓ Early customer feedback
 - ✓ Team and release plan fixed, goal to deliver maximum value with given capacity
 - ✓ Functionality delivered at the end depends on prioritization during delivery time
- **Team:**
 - ✓ Team & Product Owner empowered to decide on priorities within the guardrails of its mission
- **Use:**
 - ✓ VUCA environment - (volatile, uncertain, complex, ambiguous)

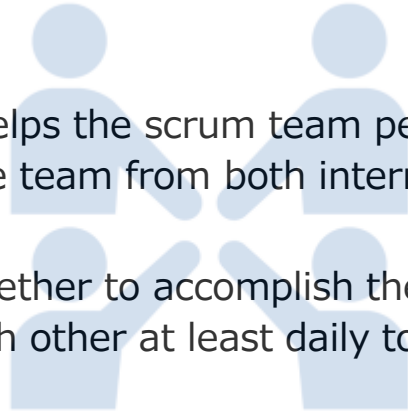
Waterfall

- **Process:**
 - ✓ Linear, sequential process
- **Time/ Resource/ Scope:**
 - ✓ Full solution delivered at once
 - ✓ Requirements fixed at the start
- **Team:**
 - ✓ Goal to deliver agreed requirements within given time & resources
- **Scope:**
 - ✓ Scope and priorities decided externally to the team

The Agile Structure



- **The team that makes up the so called “Scrum team”**
- **Product Owner**
 - ✓ Maintains the product backlog and to maximize the value the product creates for the users.
 - ✓ Looks at the vision, meeting with stakeholders and customers, and knowing when to say “no”.
- **Scrum Master**
 - ✓ The scrum master helps the scrum team perform at their highest level.
 - ✓ They also protect the team from both internal and external distractions.
- **Development Team**
 - ✓ Developers work together to accomplish the sprint goal.
 - ✓ Checking in with each other at least daily to inspect and adapt their plan.



The Agile Structure



- **Sprint Planning**
 - This ceremony is the Scrum Team's first step for sprint success. The Product Owner takes the product backlog to this event and discusses it with the Development Team.
- **Stand-up**
 - All members of the Development Team should inform everyone else about how work is going. Due to time restrictions, this event shouldn't be that detailed.
- **Sprint Review**
 - As a consequence of this ceremony and the feedback, the Product Owner might need to adjust the product backlog. They might also release product functionality if it's already complete.
- **Sprint Retrospective**
 - Discuss what went well throughout the sprint and what went wrong. So, the goal of the Sprint Retrospective is to gather rapid feedback for continuous improvement in terms of process.

Workflow - timeline

- **Sprint 1 (Oct2022 - Nov2022):**
 - Understand datasets required for ophthalmology extension of Admiral
 - Create rough specifications
 - Add ophthalmology specific test data
- **Sprint 2 (Nov2022 – Dec2022):**
 - Identify ADaMs to target for ophthalmology
 - Identify derivations/ functions required



Workflow - timeline

- **Sprint 3 (Jan2023 - Feb2023):**
 - Develop utility functions
 - Develop test data/template programs
- **Sprint 4 (Feb2023):**
 - Develop documentation
 - Complete testing
- **Package sent for review on 13th March and released 0.1.0 on CRAN on 15th March**
- **{Admiralophtha} 0.2.0 released 12th Jun, 0.3.0 released 19th Sep**



Platform, Datasets and Functions



rstudio

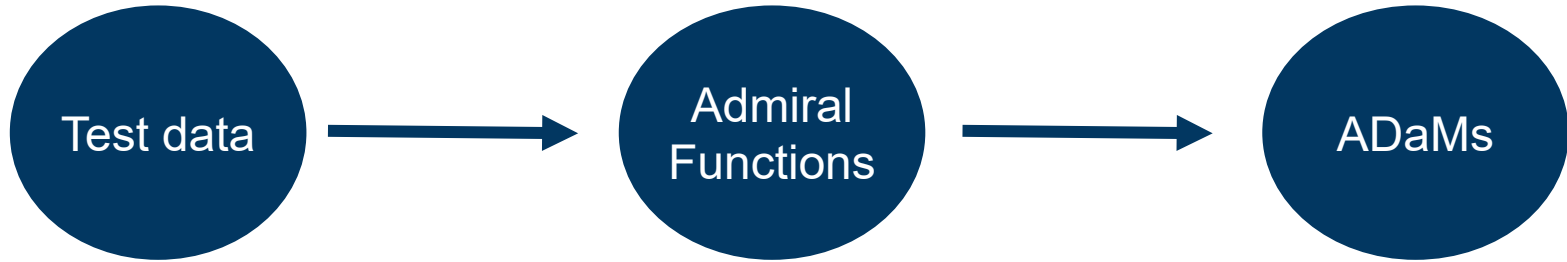


{admiralophtha} - Git



{admiralophtha}

Platform, Datasets and Functions



{Admiralophtha}

Way of working

Github

Product Solutions Open Source Pricing

Search or jump to... Sign in Sign up

pharmaverse / **admiralophtha** Public

generated from [pharmaverse/admiraltemplate](#)

Notifications Fork 4 Star 11

<> Code **Issues 5** Pull requests 3 Actions Projects Security Insights

is:issue is:open Labels 18 Milestones 0 **New issue**

5 Open ✓ 93 Closed Author Label Projects Milestones Assignee Sort

- General Issue: Review ahead of 1.0 release of admiral and admiralophtha **Release 1.0** 1 1
#204 opened 3 weeks ago by manciniedoardo
- Create template program for ADLLQ **Future releases**
#125 opened on Mar 23 by manciniedoardo
- New functions: Convert Snellen Score to LogMAR (and back) **documentation** **Future releases** **good first issue**
#122 opened on Mar 22 by manciniedoardo

Way of working

Github

| 5 Open | 93 Closed | Author | Label | Projects | Milestones | Assignee | Sort |
|---|-------------------------------------|--------|-------|----------|------------|----------|------|
| Documentation: Update release schedule on website | documentation Priority Release 2 | | | | | | |
| Chores: Add new contributors to DESCRIPTION file, add header to NEWS.md 0.2.0 section | Priority Release 2 | | | | | | |
| Bug: pkgdown searchbar is broken when searching for a function | bug Priority Release 2 | | | | 1 | | 1 |
| General Issue: AVALU = "letters" across all parameters in admiralophtha_adoe | Priority Release 2 | | | | | | |
| General Issue: Add OECAT, OESCAT to ADOE, ADBCVA lookup tables in template | good first issue Release 3 | | | | 1 | | |
| General Issue: Update to derived parameters in AD, CVA template | good first issue Priority Release 2 | | | | | | 2 |
| Documentation: Add references to formulas for conversion functions | documentation Future releases | | | | | | |

Way of working

Github



manciniedoardo commented on Apr 27

Collaborator ...

Background Information

When deriving LogMAR Score Parameters: DTYPE should be missing in this case as new parameters were created (not derived records within the same parameter).

Also, as a general rule when a new record is derived from a single record in the dataset, any variable values from the original record that do not change and that make sense in the context of the new record (e.g., --SEQ, VISIT, VISITNUM, --TPT, covariates, etc.) should be retained on the derived record. So, VISIT, VISITNUM, OEDY and OEDTC shouldn't be set to missing afterwards.

Definition of Done

No response



manciniedoardo added **good first issue** **Release 2** **Priority** labels on Apr 27

Way of working Github



ukey1025 commented on May 19 • edited

Collaborator

Hi @manciniedoardo,

I could modify LogMAR score related codes in ADBCVA template. However, I am not sure about following problem.

So, VISIT, VISITNUM, OEDY and OEDTC shouldn't be set to missing afterwards.

The following codes set to missing for VISIT, VISITNUM, OEDY, and OEDTC. Would I delete and/or modify here?

```
# Set SDTM variables back to missing for derived parameters
mutate(
  VISIT = ifelse(PARAMCD %in% c("SBCVALOG", "FBCVALOG"), NA_character_, VISIT),
  VISITNUM = ifelse(PARAMCD %in% c("SBCVALOG", "FBCVALOG"), NA, VISITNUM),
  OEDY = ifelse(PARAMCD %in% c("SBCVALOG", "FBCVALOG"), NA, OEDY),
  OEDTC = ifelse(PARAMCD %in% c("SBCVALOG", "FBCVALOG"), NA_character_, OEDTC)
```



I would appreciate it if you could give me some advice.



mancinedoardo commented

Background Info

When deriving LogMAR (not derived records) Also, as a general rule the original record for VISITNUM, --TPT, cc shouldn't be set to

Definition of Done

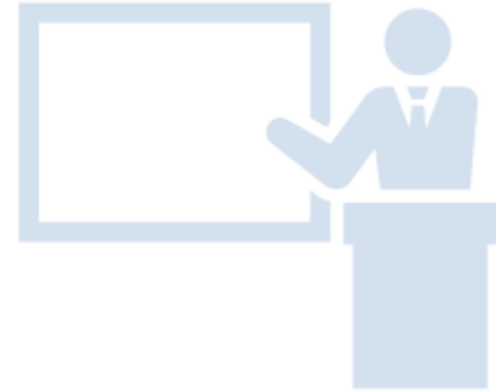
No response



mancinedoardo added **good first issue** **Release 2** **Priority** labels on Apr 27

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Went well

- The activities themselves were easy to carry out because the admiral team was very supportive
- I had little knowledge about ophthalmology study and Github, but the workflow was established so that even beginners could follow it.
- There were weekly catch-up meetings to check progress, and collaboration was easy.



Did not go well / Challenges

- The timeline was changed several times. The project did not proceed as expected. (Difficulty in collaboration with other companies)
- Some app could not be accessed due to IT policy.



Next steps



- We are developing {admiralophtha} 0.4.0

| Release Schedule | Phase 1- Date and Packages | Phase 2- Date and Packages |
|------------------|-----------------------------------|---------------------------------|
| Q4-2023 | December 4th | December 11th |
| | {pharmaversesdtm} | {admiralonco} |
| | {admiraldev} | {admiralophtha} |
| | {admiral} | |

- I would like to increase the {admiral} activities in Japan.
 - ✓ Please join **Slack** - for informal discussions, Q&A and building our user community.
 - ✓ Please access **Github Issues** - for direct feedback, enhancement requests or raising bugs

References

- Introduction:

<https://pharmaverse.github.io/admiral/index.html>

- Get Started:

<https://pharmaverse.github.io/admiral/articles/admiral.html>

- Prog strategy for devs:

https://pharmaverse.github.io/admiral/articles/programming_strategy.html





Thank you

