Automating Output Slide Decks for Dose Escalation Meetings

Developing the AutoslideR R package to support dose escalation meetings

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Background and rationale

Supporting Dose Escalation Meetings

- **Dose escalation** refers to the process of gradually increasing the amount or concentration of a medication that is given to a patient.

- Current way: Manual process of writing code to create outputs, then type or paste to a slide deck.

- A data science group initiative (N = 6) was set up to automate and streamline this process.

- Potential benefits:
  - Reduce the amount of work and required time to create slides
  - Reduce risk of errors from manual typing or copying

AutoslideR

- An R package created within Roche to automate the Study Results Endorsement Plan (SREP) meeting.
- Shared philosophies of automatic slide generation with our initiative, although the slide templates cover different phases of clinical trials.
- Reached out to product owner, who welcomed the idea of expanding features of AutoslideR.
- July 2023: Joined the AutoslideR development team to further develop dose escalation templates within AutoslideR machine.

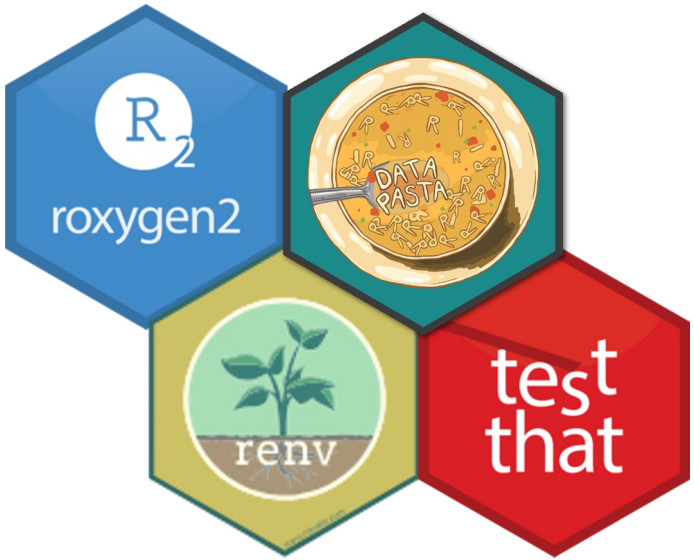
Package development

Modus operandi

- Biweekly (i.e., every two weeks) stand-ups to share progress and blockers.
- Gitlab as collaborative workspace.
- Created a list of issues on Gitlab based on the list of desired output templates for dose escalation meetings.
- Self-assign issues to work on -> create merge requests for approval.

Toolbox for package development

- **renv** - helps ensure reproducibility of project environments
- **testthat** - makes unit testing fun and satisfying.
- **roxygen2** - insert Roxygen skeletons for documentation
- **datapasta** - Pastes tibble in readable format (for unit test writing)
- **CI/CD** - ensures that changes introduced do not break the existing package



Results

What have we achieved so far?

- So far, we have produced 21 templates for use in dose escalation meetings, utilising ADaM data
- The user sets up their autoslideR script in the following way:

```
# Load libraries
library(rsvg)
library(nestcolor)
library(autoslideR)
library(dplyr)
library(scda.2022)

# Source preprocessing function
source("helper/preprocess.R")


# Now read in the data
data <- synthetic_cdisc_data("latest") %>%
  preprocess()

# Give path to spec file
spec_file <- file.path("spec_scda.yml")

# Load filters
filters::load_filters(file.path("filters.yml"), overwrite = TRUE)

# Run outputs
spec_file %>%
  read_spec() %>%
  generate_outputs(datasets = data) %>%
  decorate_outputs(version_label = NULL) -> outputs

# Generate slides from outputs (using theme and format of choice)
outputs %>%
  generate_slides(outfile = "dose_scda.pptx",
                  template = "themes/dose_theme.pptx",
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Specification File

```yaml
- program: t_dm_slide
  titles: Demographic Table
  footnotes: ''
  args:
    vars: ["AGE", "SEX", "RACE"]
  suffix: SE
- program: t_ae_slide
  titles: AE Table
  footnotes: ''
  suffix: SE
- program: l_ae_slide
  titles: AE Listing
  footnotes: Investigator text for AEs encoded using MedDRA version 26.1. Only treatment emergent AEs leading to study treatment discontinuation are displayed.
    (1) Outcome - 1 = Fatal; 2 = Not recovered/not resolved; 3 = Recovered/resolved; 4 = Recovered/resolved with sequelae; 5 = Recovering/resolving; 6 = Unknown.
    (2) Action taken - 1 = Dose increased; 2 = Dose not changed; 3 = Dose reduced; 4 = Drug interrupted; 5 = Drug withdrawn; 6 = Not applicable; 7 = Unknown; 8 = Multiple."'
  suffix: SE
- program: g_eg_slide
  titles: Heart Rate Plot
  footnotes: ''
  suffix: HR_SE
```

- **program** - Name of template (or study-specific program)
- **titles** - Title to display on slide
- **footnotes** - Footnote to display on slide
- **suffix** - Filter to apply to dataset(s)
- **args** - Additional arguments that can be passed to the output function itself (e.g. specific variables to include)

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Example Slidedeck Produced by autoslideR

Demographic Table, Safety-Evaluable Patients

	A: Drug X (N=4)	B: Placebo (N=2)	C: Combination (N=2)	All Patients (N=8)
Age				
Median	37.00	28.50	30.00	34.50
Min - Max	34.0 - 47.0	25.0 - 32.0	25.0 - 35.0	25.0 - 47.0
Sex				
F	1 (25%)	1 (50%)	1 (50%)	3 (37.5%)
M	3 (75%)	1 (50%)	1 (50%)	5 (62.5%)

Demographic Table, Safety-Evaluable Patients (cont.)

	A: Drug X (N=4)	B: Placebo (N=2)	C: Combination (N=2)	All Patients (N=8)
Race				
ASIAN	1 (25%)	0	0	1 (12.5%)
BLACK OR AFRICAN AMERICAN	2 (50%)	2 (100%)	0	4 (50%)
WHITE	1 (25%)	0	2 (100%)	3 (37.5%)
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0	0
MULTIPLE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
OTHER	0	0	0	0
UNKNOWN	0	0	0	0

AE Table, Safety-Evaluable Patients

MedDRA System Organ Class MedDRA Preferred Term N (%)	A: Drug X (N=4)	B: Placebo (N=2)	C: Combination (N=2)
cl D.1	3 (75.0%)	0	2 (100%)
dcd D.1.1.1.1	2 (50.0%)	0	2 (100%)
dcd D.1.1.4.2	2 (50.0%)	0	1 (50.0%)
cl A.1	3 (75.0%)	0	1 (50.0%)
dcd A.1.1.1.2	2 (50.0%)	0	1 (50.0%)
dcd A.1.1.1.1	1 (25.0%)	0	1 (50.0%)
cl B.1	2 (50.0%)	2 (100%)	0
dcd B.1.1.1.1	2 (50.0%)	2 (100%)	0
cl B.2	3 (75.0%)	0	1 (50.0%)

AE Listing, Safety-Evaluable Patients

Center/Patient ID	Adverse Event MedDRA Preferred Term	Date of First Study Drug Administration	Serious	Caused by Study Drug	Analysis Toxicity Grade	Action Taken (2)
BRA-1/id-134	dcd B.2.1.2.1	04NOV2020	No	No	3	2
BRA-1/id-134	dcd D.1.1.4.2	04NOV2020	No	No	3	2
BRA-1/id-134	dcd A.1.1.1.2	04NOV2020	Yes	No	2	2
BRA-1/id-134	dcd A.1.1.1.2	04NOV2020	Yes	No	2	5

Investigator text for AEs encoded using MedDRA version 26.1. Only treatment emergent AEs leading to study treatment discontinuation are displayed. (1) Outcome - 1 = Fatal; 2 = Not recovered/not resolved; 3 = Recovered/resolved; 4 = Recovered/resolved with sequelae; 5 = Recovering/resolving; 6 = Unknown. (2) Action taken - 1 = Dose increased; 2 = Dose not changed; 3 = Dose reduced; 4 = Drug interrupted; 5 = Drug withdrawn; 6 = Not applicable; 7 = Unknown; 8 = Multiple."'

AE Listing, Safety-Evaluable Patients (cont.)

Center/Patient ID	Adverse Event MedDRA Preferred Term	Date of First Study Drug Administration	Serious	Caused by Study Drug	Analysis Toxicity Grade	Action Taken (2)
BRA-1/id-141	dcd B.2.1.2.1	25JUL2020	No	No	3	1
BRA-1/id-141	dcd D.2.1.5.3	25JUL2020	No	Yes	1	1
BRA-1/id-141	dcd A.1.1.1.1	25JUL2020	No	No	1	3
BRA-1/id-141	dcd A.1.1.1.2	25JUL2020	Yes	No	2	2
BRA-1/id-141	dcd A.1.1.1.1	25JUL2020	No	No	1	1
BRA-1/id-141	dcd D.1.1.1.1	25JUL2020	Yes	Yes	5	6

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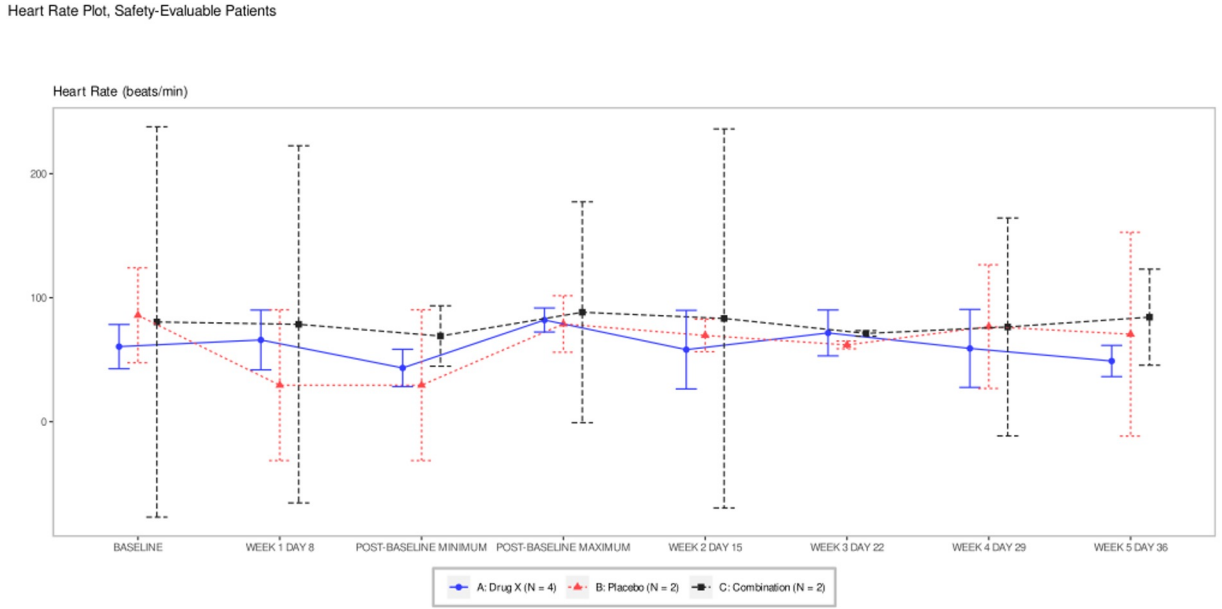
Heart Rate Plot, Safety-Evaluable Patients



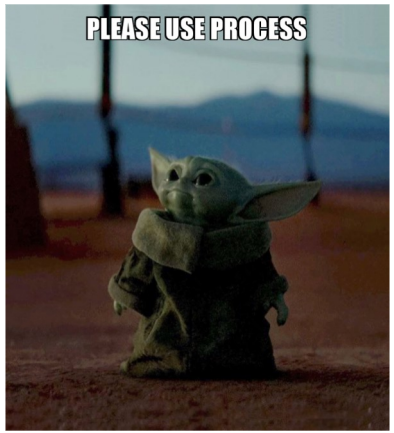
Reflections

Kai’s Reflections

- Understand R packages better
- Appreciate Git/Gitlab for collaboration
- Embrace imperfections - *“JUST SEND THE MERGE REQUEST”*
- Overcome motivational slumps with deadlines
- Challenges arising from team members leaving or retiring.
    - Mitigate knowledge loss through effective knowledge transfer strategies.
    - Importance of well-documented meeting minutes.

Miles' Reflections

- Communication (lots of stakeholders involved)
- Changing priorities (lack of resource at times due to team availability)
- More clinical input earlier on would have been useful
- Better understanding of what goes into an R package (very different from regular programming)
- Creating the product is only half the battle, you've still got to convince people to use it!



Future Directions

Future Directions - What's next?

- SDTM data - templates relying on ADaM data can be an issue for dose escalation meetings
- Feedback from pilot studies
- Validation within the next 6 months
- Open source?
- User documentation
- Strategy for implementing study specifics into templates? - Careful thought needed to allow sufficient flexibility but keeping a standard way of working

Acknowledgements

- Joe Zhu (product owner of autoslideR)
- NEST team
- Dietmar Voltz
- Elisabeth Deutschmann
- Stefan Pascal Thoma
- XiaoLi Duan
- Elisabeth Gruendl
- David Ward
- Josie Jackson
- Edoardo Mancini
- Tim Barnett

Doing now what patients need next