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The process of clinical drug development is highly regulated

In clinical drug development the goal is produce reliable evidence on whether or not a product is both safe and efficacious

This process involves multi-disciplinary stakeholders coming together to review evidence which is generated a highly regulated manner.

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i Working a regulated way as a statistician or programmer in pharma has three key pillars?

1. Traceable
2. Reproducible
3. Accurate

How do we manage tech evolution and adaption in pharma?

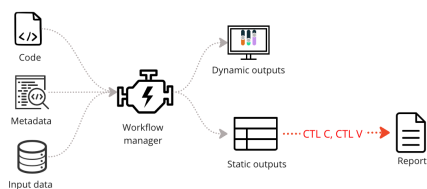
- Big-bang, disruptive change takes time in a regulated environment.
- Non-disruptive change can help us make incremental progress to get ready for change.

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💡 Non-disruptive change for automated report generation

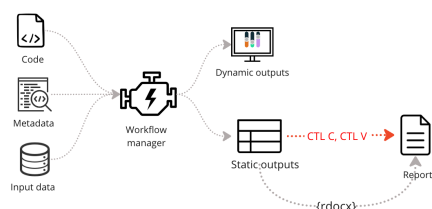
Let's bring the modern tooling and practices to static document generation so that we can retain reproducibility and work at scale.

From data to evidence



- Report generation relies on copying and pasting static outputs into a document
- This can be error prone, time consuming and doesn't scale.

Additional pathway using {rdocx}



- We created a new package {rdocx} and process that leverages good data science practices that can generate company compliant reports

Use case: sample size estimation and reporting

i What: Sample size report generation

Our trial statisticians estimate and document the sample size for studies using a company template in docx format. It is mandatory that the report complies with the company template.

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💡 How: successful development and change is so much more than good code

1. Get experts onboard (compliance, statisticians)
2. Co-design
3. Leverage good software development practices
4. Develop incrementally, demo-ing regularly

Let's make a title page

Mandatory elements are represented as R6 classes where each attribute has a unique input requirement that goes through a series of checks.

```
tp <- rdocx::TitlePage$new(
  compound= "Compound",
  study_number = "Study number",
  study_title = "Study title",
  doc_status = "Final",
  release_date = "01-Jul-2024",
  n_pages = "10")

# Generates the title page
tp$get_title_page()
```



Clinical Development

Compound

Study number

Study title

Sample Size Calculation

Author: Statistician

Document type: Sample Size Calculation

Document status: Final

Release date: 01-Jul-2024

Number of pages: 6

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Template Version 3.0, Effective from 20-Jul-2023

Let's make a change log

Mandatory elements are represented as R6 classes where each attribute has a unique input requirement that goes through a series of checks.

```
# Initiate change log table
changelog_table <- rdocx::ChangelogTable$new()

row_1 <- rdocx::ChangelogTableRow$new(
  date = '01-Feb-2024',
  time_point = 'Before protocol finalization',
  reason_update = 'Creation of first version',
  outcome_update = 'NA - First version',
  section_title_impacted = 'NA')

changelog_table$add_row(row_1)
```

Date	Time point	Reason for update	Outcome for update	Section and title impacted (Current)
01-Feb-2024	Before protocol finalization	Creation of first version	NA - First version	NA

Let's make a complete report

Check document template and render:

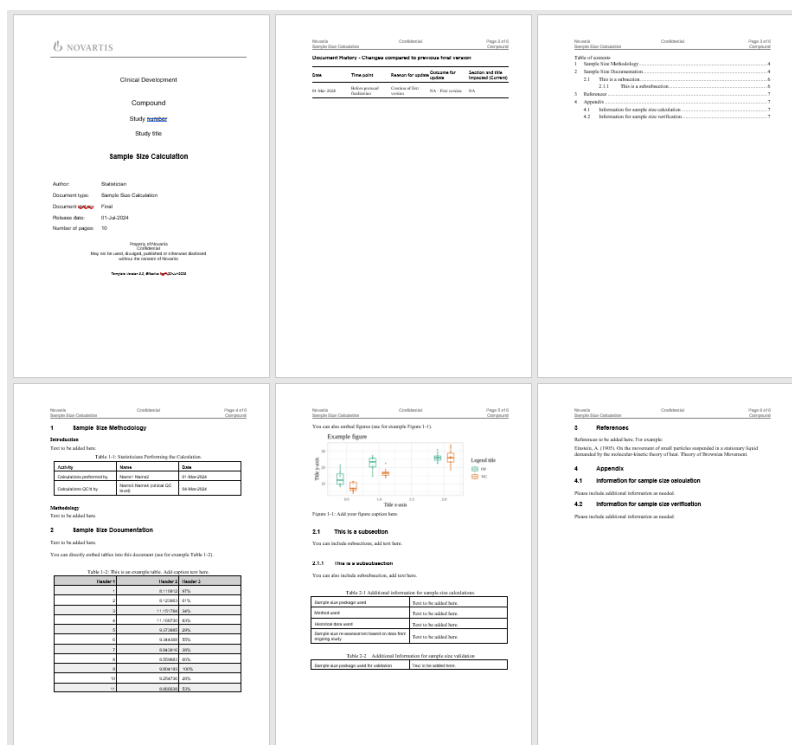
```
rdocx::print_ss_template_version()
```

```
rdocx::rmd_render(
  rmd_filename = "path/to/rmd_file",
  output_path = "path/to/final_docx",
  report_type = "sample_size",
  version = 00
)
```

A log file will be generated documenting the following:

- User, system, date and time
- Final document name and location
- Location of R packages and R session info (`sessionInfo()`)

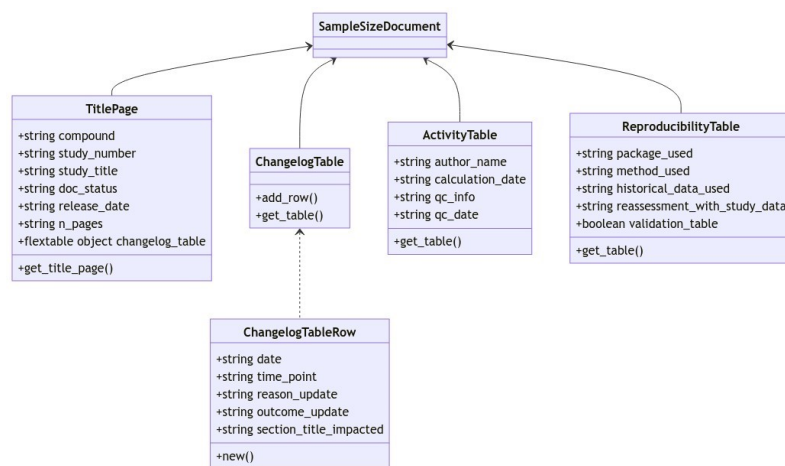
Inspect compiled document



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We embedded {rdocx} in good software development practices

We use object-oriented (R6 classes) to structure our package.



We embedded {rdocx} in good software development practices

We could create many assertions to do perform upfront checks.

```
tp <- rdocx::TitlePage$new(
  compound= "Compound",
  study_number = "Study number",
  study_title = "Study title",
  doc_status = "Final",
  release_date = "01-07-2024",
  n_pages = "10")
```

```
Error in check_string_is_date(release_date) :
  `Date` was not provided in the expected format (%d-%b-%Y). For example: 01-Oct-2023
```

We embedded {rdocx} in good software development practices

We have automated tests and check for each incremental change in to the rdocx package.

```
3 Preparing the "shell" executor 00:00
4 Using Shell executor...
6 Preparing environment 00:00
7 Running on dc-gitlab-runner-r410-42-p2nff...
9 Getting source from Git repository 00:01
10 Fetching changes with git depth set to 20...
11 Reinitialized existing Git repository in /gitlab-runner/builds/53wtlnsi/0/scc/open-source-for-submission/rdocx/.git/
12 Checking out 1d9b178d as main...
13 Removing covr/
14 Skipping Git submodules setup
16 Executing "step_script" stage of the job script 00:21
17 $ Rscript -e "devtools::test(stop_on_failure = TRUE)"
18 i Loading rdocx
19 i Testing rdocx
20 ✓ | F W S OK | Context
21 F | 0 | ActivityTable
22 ✓ | 6 | ActivityTable
23 F | 8 | ActivityTable
24 ✓ | 16 | ActivityTable
25 ✓ | 18 | ActivityTable [0.4s]
26 F | 0 | ChangeLogTable
27 ✓ | 16 | ChangeLogTable
28 F | 21 | ChangeLogTable
29 ✓ | 25 | ChangeLogTable [0.3s]
30 F | 0 | ReplaceOutputs
31 ✓ | 17 | ReplaceOutputs
INFO [12:44:06.695] Word template filena
```

What's next

- We plan to open-source our {rdocx} package with a generic template example
- We want to adapt it to more use-cases, e.g. pre-clinical safety report

Acknowledgements

- Jana Linnik (Developer and SME)
- Ines Gimeno Molina (Developer)
- Ivan Demin (Contributor)
- Maritza Cuero Melendez (Compliance)

```
<script type="text/javascript"> Reveal.on('ready', event =>
if (event.indexh === 0) document.querySelector("div.has-
logo > img.slide-logo").style.display = "none"; ); Re-
veal.addEventListener('slidechanged', (event) => if
(event.indexh === 0) Reveal.configure( slideNumber:
null ); document.querySelector("div.has-logo > img.slide-
logo").style.display = "none"; if (event.indexh === 1) Re-
veal.configure( slideNumber: 'c/t' ); document.querySelector("div.has-
logo > img.slide-logo").style.display = null; ); </script>
```