

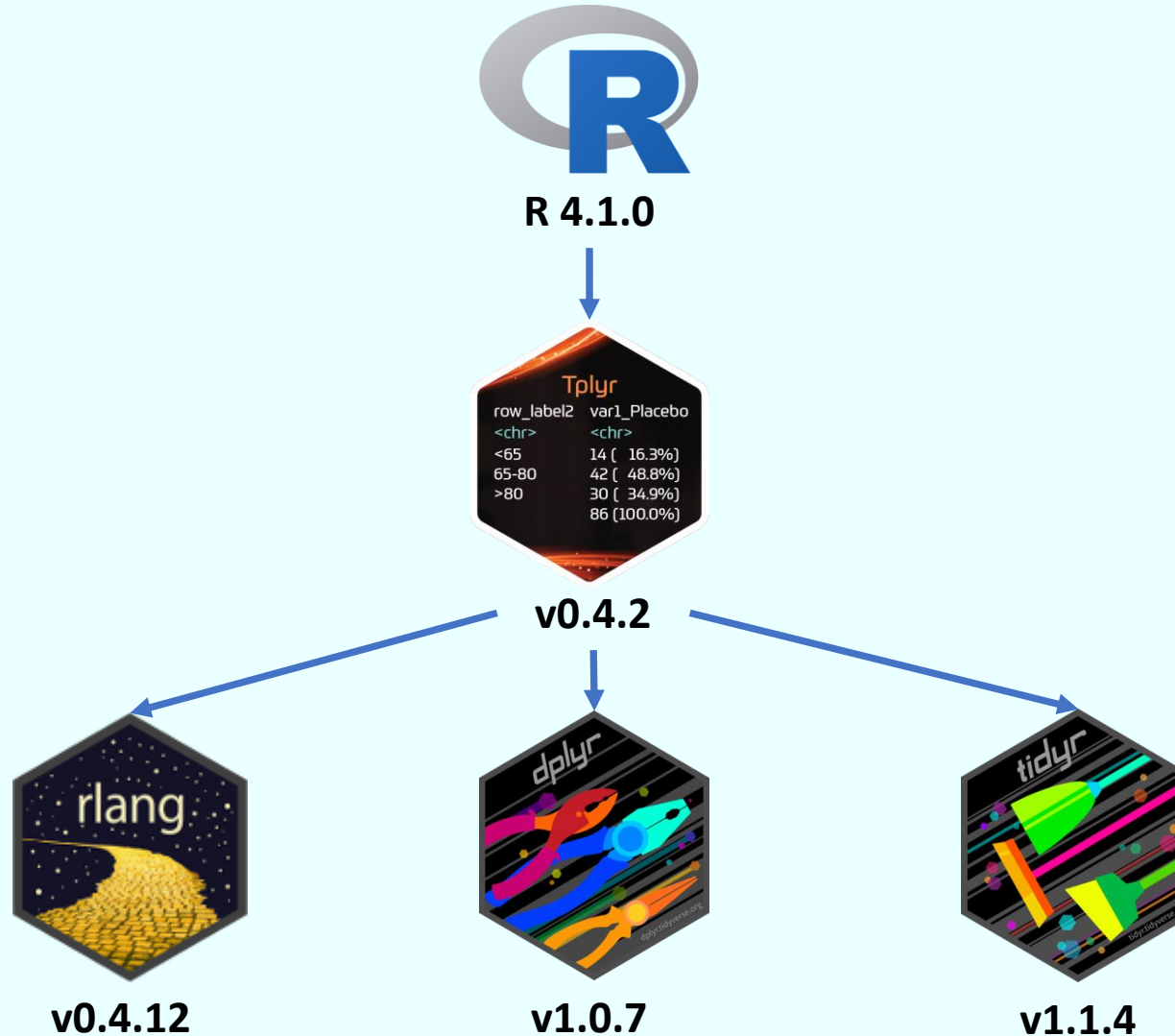
# BIOGRAPHY

Mike Stackhouse: Mike is a 2020 UC Berkeley School of Information Master of Information and Data Science (MIDS) program graduate, where he worked on projects involving computer vision, natural language processing, cluster computing, and deep learning. Previously, Michael was a senior manager of statistical programming at Covance, where he led U.S. innovation activities for the FSP department. Michael and his team at Atorus have been actively developing and releasing open-source R packages, such as pharmaRTF and Tplyr.

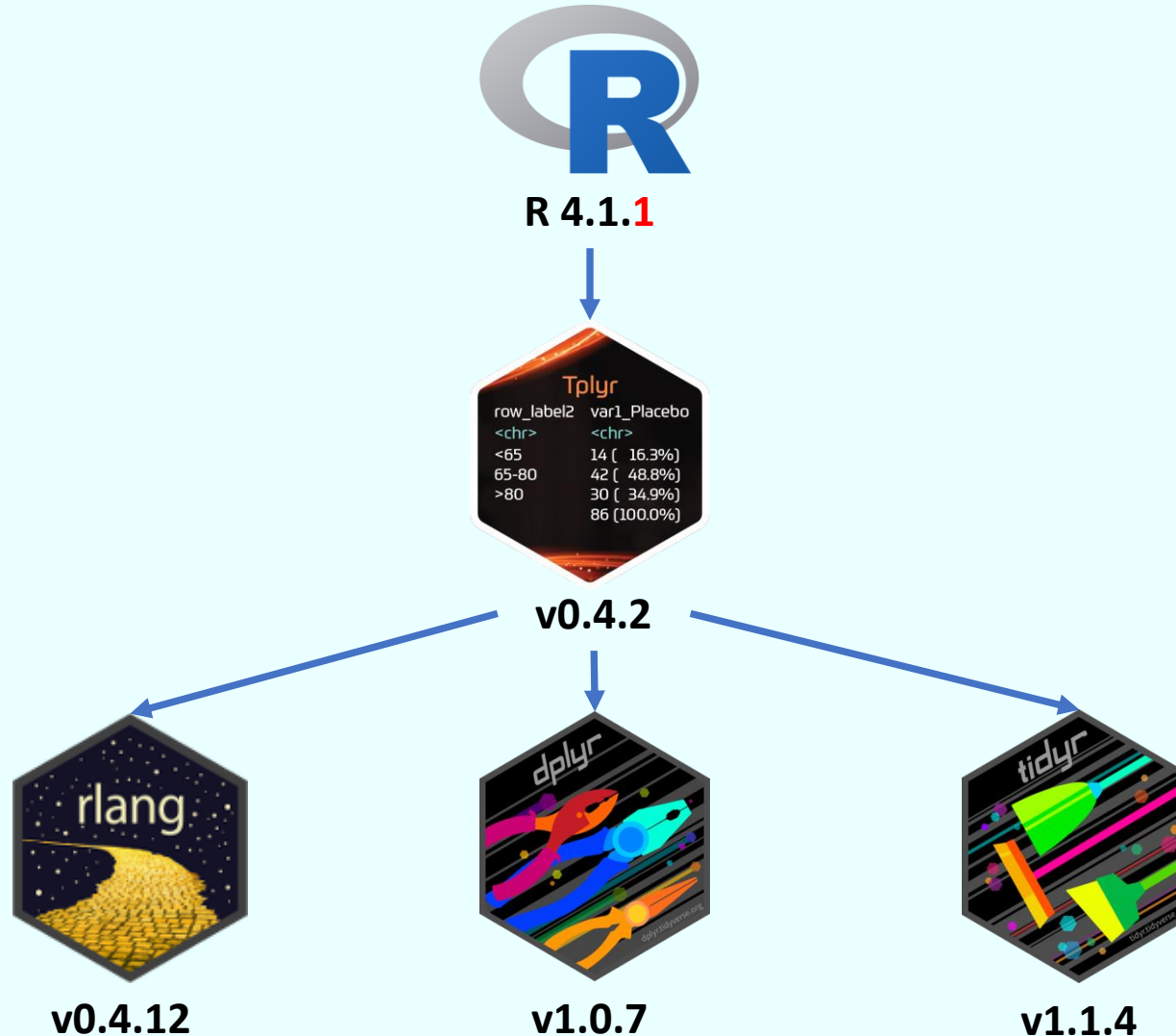
# Industry Projects

on the Validation of Open-Source

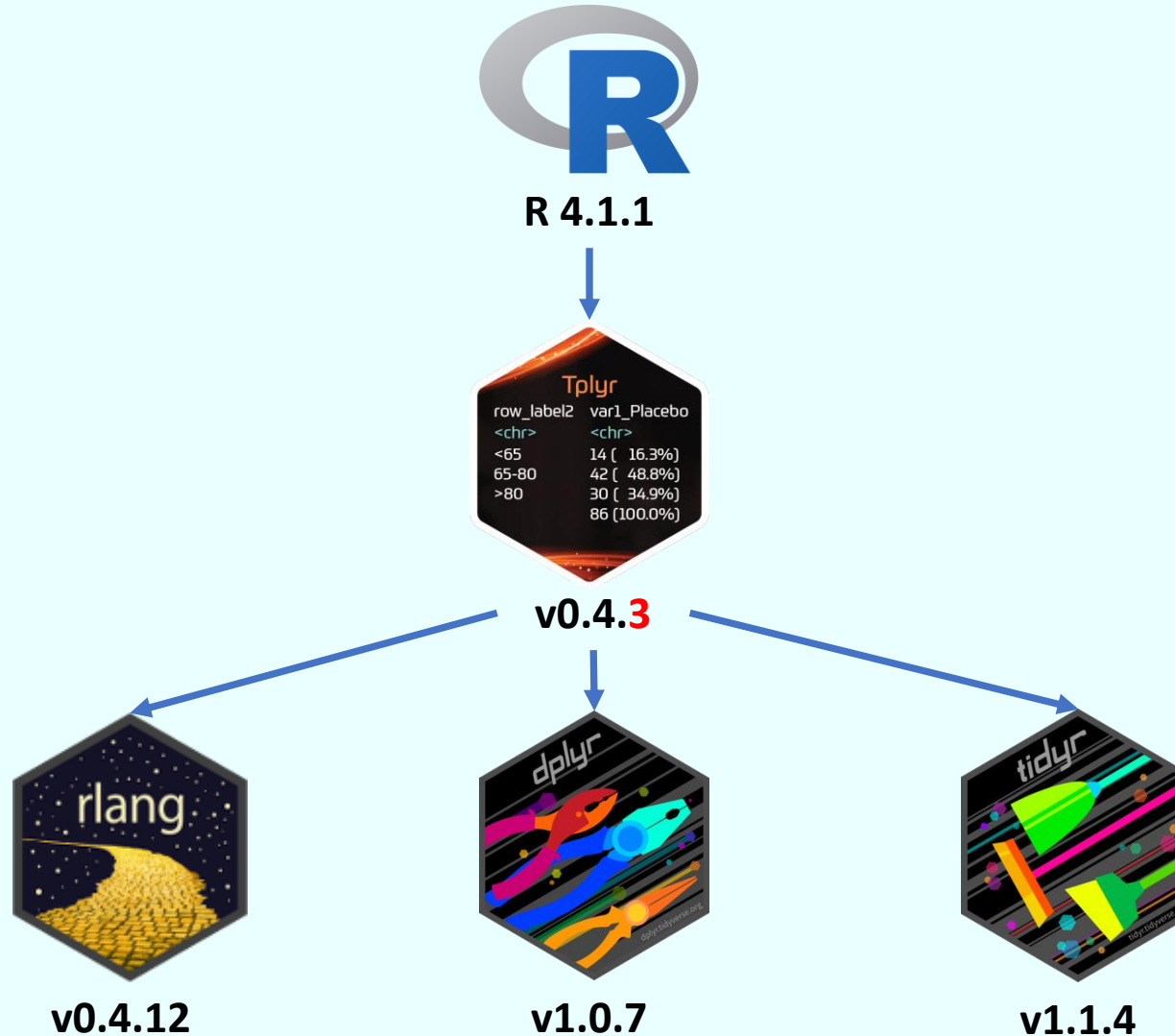
# Why is validation a challenge?



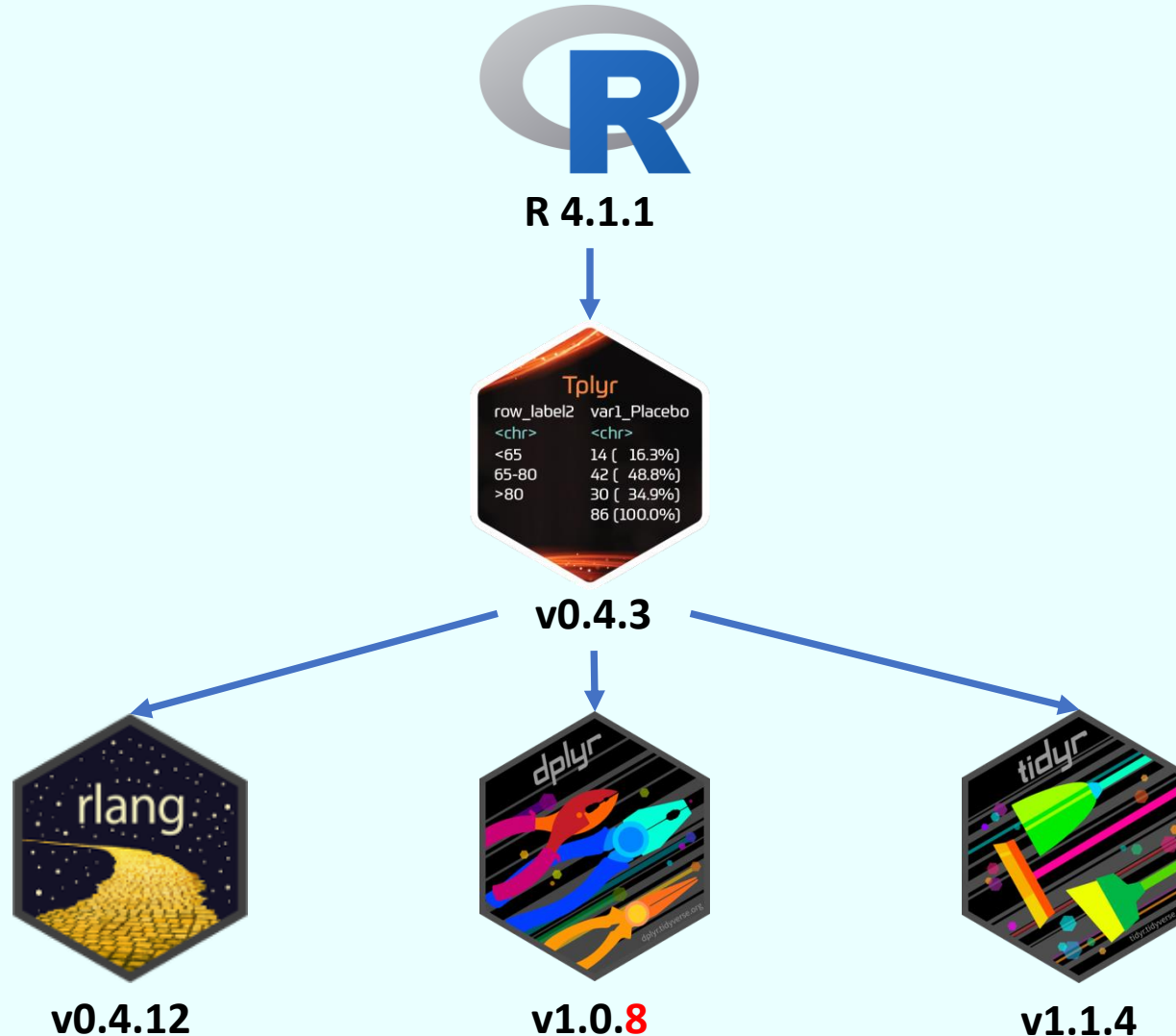
# Why is validation a challenge?



# Why is validation a challenge?



# Why is validation a challenge?



# Validation Questions

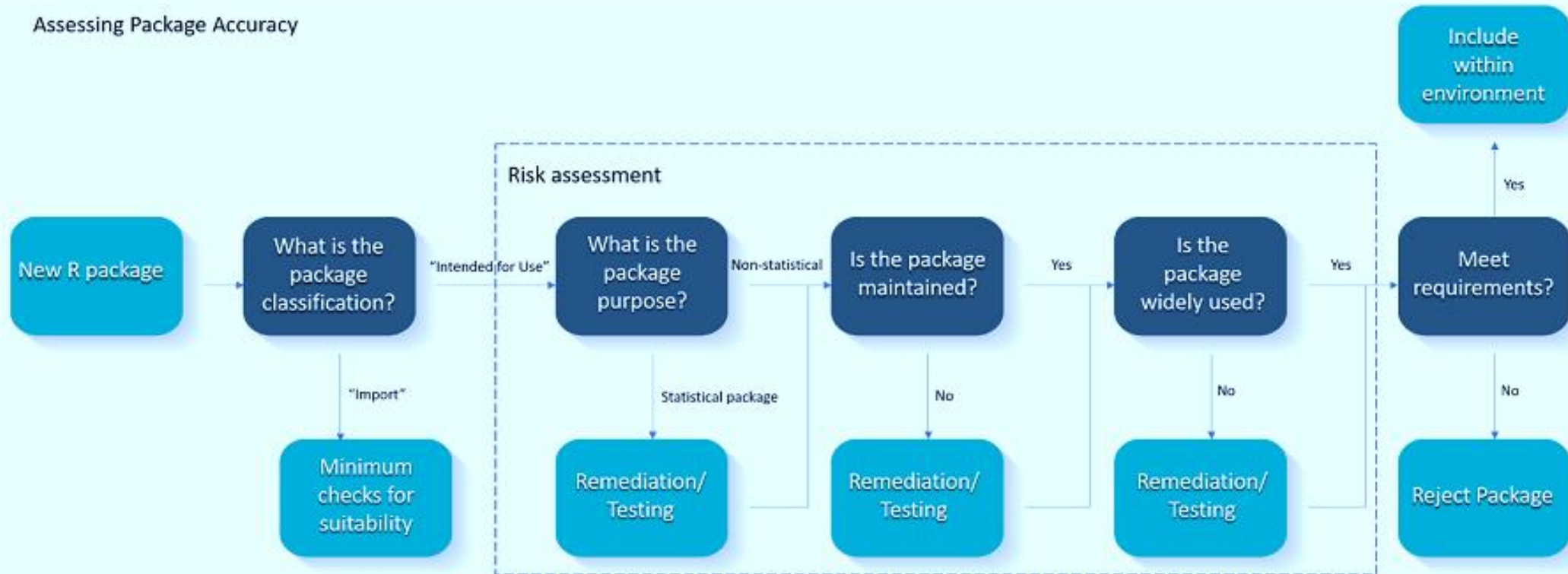
- What do we need to **validate**?
- How much **testing** do we need to do?
- How do we remain **flexible**?
- What **tools** do we have to help?
- What can we expect **post-validation**?

# General Process



# The R Validation Hub

## Assessing Package Accuracy



<https://www.pharmar.org/white-paper/>

# {riskmetric} Application

**Validation Hub** **R Package Risk Assessment App** Assessment Criteria

**Package Control Panel**

Select Package:

Select Version:

Status: **Under Review**

Score: **0.3**

Leave Your Overall Comment:

current comment:

Overall Risk:

**Maintenance Metrics**

- PRESENCE OF VIGNETTES? YES**  
The package has 0 Vignettes
- ASSOCIATED WEBSITE URL? YES**  
Website: <https://tidyr.tidyverse.org>
- NEWS? YES**  
The package has a NEWS file.
- NEWS IS CURRENT? YES**  
NEWS file contains entry for current version number
- BUGS PUBLICLY DOCUMENTED? YES**  
Bug reports URL: <https://github.com/tidyverse/tidyr/issues>
- BUG CLOSURE 36.67%**  
Percentage of last 30 bugs closed
- DOCUMENTATION 100%**  
Proportion of exported objects documented
- SOURCE CODE PUBLIC? YES**  
Source code URL: <https://github.com/tidyverse/tidyr>
- HAS A MAINTAINER? YES**  
Hadley Wickham <[hadley@rstudio.com](mailto:hadley@rstudio.com)>

**Leave Your Comment for Maintenance Metrics:**

Commenting as Andy ( Package Reviewer )

**Comments(0):**

# Package Tests

```

i Loading Tplyr
i Testing Tplyr
✓ OK F W S Context
✓ 3 build [0.4 s]
✓ 15 column_headers.R [1.2 s]
✓ 162 count [10.7 s]
✓ 2 denom
✓ 59 desc [2.1 s]
✓ 66 format.R [0.1 s]
✓ 15 functional [4.3 s]
✓ 61 get_numeric.R [0.6 s]
✓ 49 layer.R [0.2 s]
✓ 27 layering.R
✓ 36 zzz.R [3.0 s]
✓ 7 pop_data [0.2 s]
✓ 6 precision.R [0.1 s]
✓ 8 print [0.5 s]
✓ 17 properties_layer
✓ 28 riskdiff.R [1.9 s]
✓ 20 shift [0.8 s]
✓ 52 sort [4.0 s]
✓ 23 table_bindings
✓ 10 table_
✓ 20 utils.R [0.3 s]

```

---

== Results ==

Duration: 30.9 s

[ FAIL 0 | WARN 0 | SKIP 0 | PASS **686** ]

# Tools and Utilities

# R Package Validation and {valtools}



<https://phuse-org.github.io/valtools/>

## 5 Example Specification and Testing

### 1. Specification 1: Tell a Joke

		Specification 001		
		S1.1	S1.2	S1.3
Presentation Success Test Cases 001	T1.1	x	x	x

- *Specifications*

- 1.1 Presentation must explain validation procedure.
- 1.2 Presentation will be between 15-20 minutes long
- 1.3 Be entertaining, success measures by causing at least 3 people to laugh.
- 1.4 (Optional) Fame and Glamour and start branded accessories chain.


- *Test Cases*

- Setup: Create Presentation
- T 1.1 Test that specifications 1.1, 1.2, and 1.3 are met by practicing presentation on unsuspecting co-workers
  - \* Present to a captive audience of coworkers and later your significant other
  - \* T 1.1.1 Test that the presentation was informative by asking what your audience learned.
  - \* T 1.1.2 Time the presentation and make sure it was between 15 and 20 minutes.
  - \* T 1.1.3 Test that you were entertaining by counting the amount of chuckles (>3)
    - T 1.1.3.1 Alternatively, eye-rolls from your significant other (>4)

- *Test Results*

Test	Results	Pass/Fail
T1.1.1	As expected	Pass
T1.1.2	As expected	Pass
T1.1.3	As expected	Pass

# {thevalidatoR}



GitHub Action


## R Package Validation Report

v1.0 Pre-release

**thevalidatoR**

- An R Package Validation Report
  - Description
  - Action Type
  - Author
  - Inputs
  - Outputs
  - How to use
    - Quickstart
    - V1.0 Examples
      - rbmi
      - admiral

### An R Package Validation Report

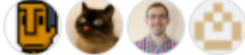


Use latest version

Stars

☆ Star 4

Contributors



Categories

Continuous integration Code quality

Links

- insightengineering/thevalidatoR
- Open issues 3
- Pull requests 0
- Report abuse

# R Environment System Qualification

```
knitr::kable(df)
```

IQ	OQ_Tests	OQ_Examples	OQ_Vignettes	Installed_Tests	Installed_Examples	Installed_Vignettes
Pass	Pass	Pass	Pass	Fail	Fail	Fail

## Package Qualifications

Summaries of installed packages and their qualification results.

```
knitr::kable(installed_test)
```

Package	Test	Examples	Vignettes
askpass	Pass	Pass	Pass
assertthat	Pass	Pass	Pass
backports	Pass	Pass	Pass

<https://github.com/phuse-org/SystemValidation>

# Post-validation



# Clinical Statistical Reporting in a Multilingual World



Document and build a repository of common analyses

Outline differences in implementation  
Document differences in capabilities and known discrepancies



Establish a general framework for approaching new analyses

Recommend approach for investigation  
Establish a framework for effectively communicating findings or potential issue areas

# Noteworthy Mentions

# R Consortium Initiatives



## **R Tables for Regulatory Submissions (RTRS)**

Aiming to help support and enhance R's ability to produce regulatory tables

Participation from various pharma, CRO, and R table package authors



## **R for Regulatory Submissions**

Pilot Submission through eCTD

Testing use of Merck package {pkglite}

Name: Mike Stackhouse

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Twitter: @mike\_at\_atorus

LinkedIn: <https://www.linkedin.com/in/michael-s-stackhouse/>