

R Package Validation Framework

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Is it
Validated?

Establishing documentary evidence that your software performs a

Procedure

Process

Activity

in compliance with specifications to a high degree of assurance

What is
Validation?

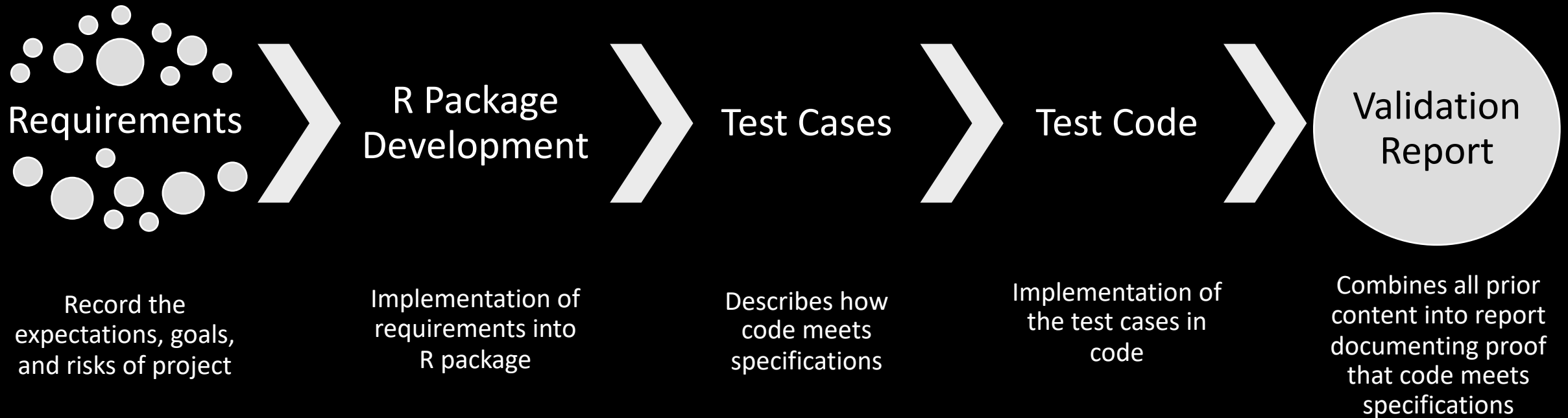
Why do we care about Validated R packages?

- FDA Submission
- Create a unified approach to similar problems
- Documentation and distillation of knowledge
- Improve trust, quality, and safety of code

Validation can be a high bar

- Fill out a form for specifications, planned uses, environments
- Write Code and record function authorship in some excel file
- Get another form to document test cases, testing environment, ...
- Maybe the last form to show that testing plan is comprehensive
- Manually evaluate tests and screenshot results
- Review documentation, combine into final report and signoffs for release

R Package Validation Framework



Validation Report

2 Validation Environment

Environment Detail	Environment Record
R Version	R version 4.0.2 (2020-06-22)
Dependency Versions	testthat (v2.3.2)
	knitr (v1.29)
	rmarkdown (v2.3)

3 Authorship

3.1 Specifications

Specification Name	Last updated by	Last updated date
Specifications Presentation Success	Ellis Hughes	2030-01-01

3.2 Functions

Function Name	Last updated by	Last updated date
joke	Joe King	2030-04-01

3.3 Test case

Test Case Name	Last updated by	Last updated date
Presentation Success Test Cases 001	Ellis Hughes	2030-01-01

3.4 Test code

Test Code Name	Last updated by	Last updated date
T001		
T1.1	Jess Terr	2030-01-01

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

A rocket is shown launching from a launchpad, with a large plume of smoke and fire at the base. The rocket is white with a red stripe. The launchpad is a complex of metal structures. The sky is blue with some clouds.

PUSH BUTTON GET VALIDATED

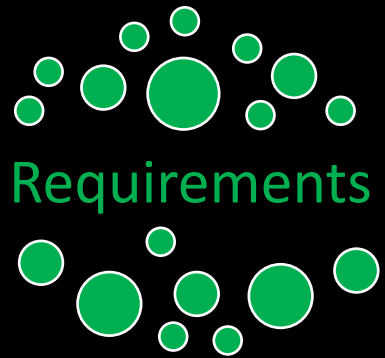
“ The framework turns validation into a transparent, easy-to-follow process that not only that simplifies validation but improves the quality of both the package and validation.

- Me

PHUSE Working Group

- White Paper
 - Distillation of framework
 - Collaboration
- R Package
 - Implementation of framework
 - Inspired by {devtools} and {usethis}

```
remotes::install_github("phuse-org/valtools")
```



Record the expectations, goals, and risks of project



R Package Development

Implementation of requirements into R package



Test Cases

Describes how code meets specifications



Test Code

Implementation of the test cases in code



Combines all prior content into report documenting proof that code meets specifications

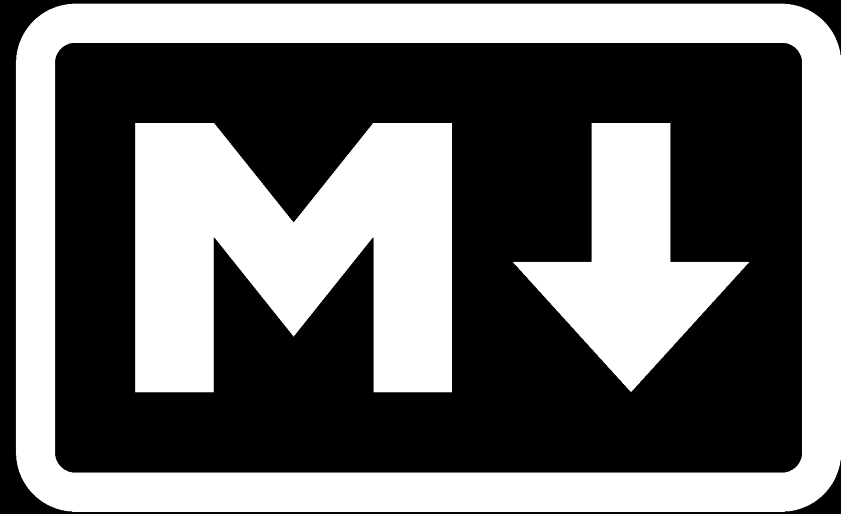
Requirements

- *Goals and Purpose*
- Risk assessment
 - **Probability** of defects
 - **Impact** when there are defects
- Provides all context required or points to references



Documenting Requirements

- **Human** and **machine** readable
- Capture editor and edit date
- Record and save within the validation folder
 - Working_dir/validation/requirements



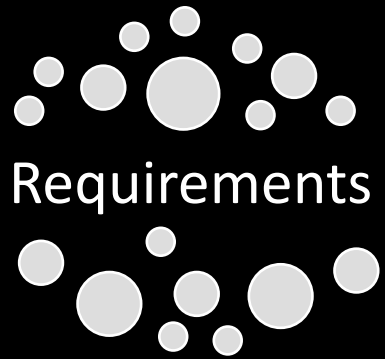
```
valtools::vt_use_req("requirement_001.md")
```

#' @title Requirements For Presentation Success

#' @editor Ellis Hughes

#' @editDate 2025/01/01

- + 1.1 Presentation must explain validation procedure.
- + 1.2 Presentation will be between 20-25 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.



Requirements

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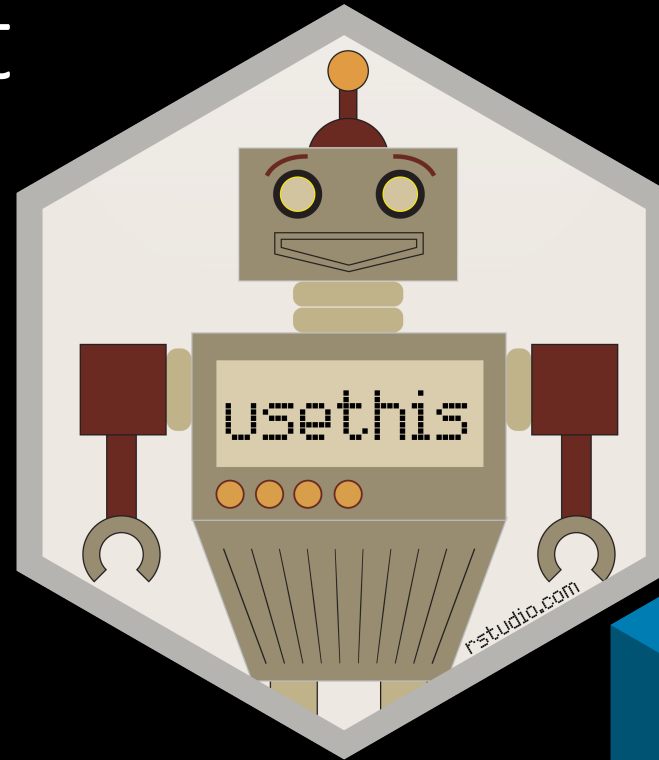


Validation Report

Combines all prior content into report documenting proof that code meets specifications

Package Development

- Follow GPP
- Documentation
 - Function manuals
 - Vignettes
- Unit testing and code review



Function documentation

- Record *with* function using Roxygen
 - Easier to remember
 - Adds to documentation

@editor

@editDate

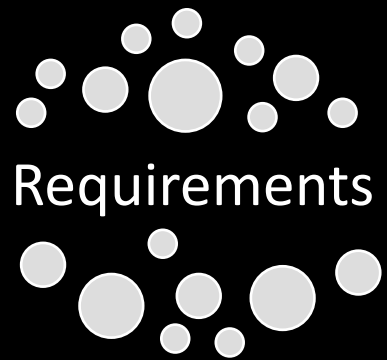


```
#' @title Deliver Jokes
#' @description
#'   Deliver jokes with punchlines. Wait 3 seconds for the punchline.
#' @param Setup Joke setup
#' @param Punchline Joke punchline
#' @examples
#' joke('To the person who stole my presentation -','I hope you do not Excel.')
#'
#' @editor Ellis Hughes
#' @editDate 2030/01/01

joke <- function(Setup, Punchline){
  print(Setup)
  Sys.sleep(3)
  print(Punchline)
}
```

```
#' @title Deliver Jokes
#' @description
#'   Deliver jokes with punchlines. Wait 3 seconds for the punchline.
#' @param Setup Joke setup
#' @param Punchline Joke punchline
#' @param wait how long to wait to serve the punchline
#' @examples
#' joke('Why did the PowerPoint Presentation cross the road?', 'To get to the other slide.')
#'
#' @editor Joe King
#' @editDate 2030/04/01

joke <- function(Setup, Punchline, wait = 3){
  print(Setup)
  Sys.sleep(wait)
  print(Punchline)
}
```



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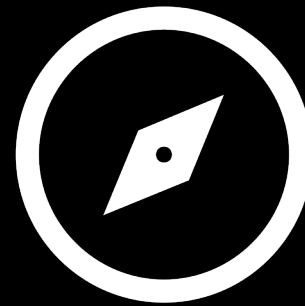
Test Cases

- Document how to prove package meets specifications
- Should represent realistic scenarios
- Every requirement must be satisfied by at least one test case
- A test case can satisfy multiple requirements

Requirement	Test Case
Requirement 1	Test Case 1, Test Case 2
Requirement 2	Test Case 2, Test Case 3
Requirement 3	Test Case 3

Documenting Test Cases

- **Human** and **machine** readable
- Capture editor, edit date, coverage
- Record and save within the validation folder
 - `working_dir/validation/test_cases`



```
valtools::vt_use_test_case("test_case_001.md")
```

```
#' @editor Ellis Hughes
#' @editDate 2030/01/01
#' @coverage:
#' T1.1: S1.1, S1.2, S1.3
```

+ _Test Cases_

+ Setup: Create Presentation

+ T 1.1 Test that requirements 1.1, 1.2, and 1.3 are met by practicing presentation on unsuspecting co-workers

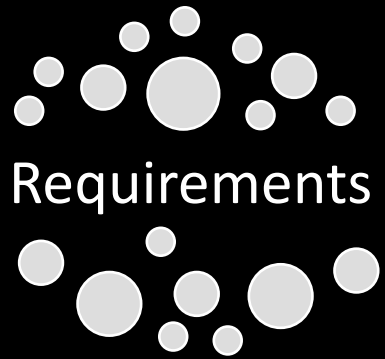
- Present to a captive audience of coworkers and later your significant other

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Test Code

- Implementation of test cases as code
- Uses {testthat} as a familiar testing framework
 - Self contained
 - Clear expectations



{testthat}

- Reporter Object
 - Captures each expectation result
 - Records test name

```
| OK F W S | Context  
| 3        | test_case_001 [3.2 s]
```

```
-- Results -----
```

```
Duration: 3.2 s
```

```
OK:      3
```

Test	Results	Pass/Fail
T1.1.1	As expected	Pass
T1.2.1	As expected	Pass
T1.2.2	As expected	Pass

Writing Test Code

- Capture editor, edit date
- Record and save within the validation folder
 - working_dir/validation/test_code

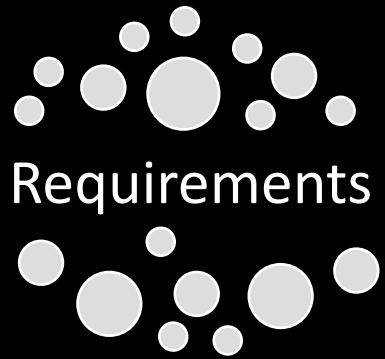
```
valtools::vt_use_test_code("test_code_001.R")
```

```
#' @title T1.1
#' @editor Jess Terr
#' @editDate 2030/01/01

test_that('T1.1',{

  joke_result <- joke('What do you call a fake noodle?','An Impasta')
  expect_true(is_dad_joke(joke_result))
  expect_true(caused_laughter(joke_result))
  expect_true(embarrassed_significant_other(joke_result))

})
```



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Validation Report

- Dynamically captures and records all elements generated across the framework
- Records testing environment, package version
 - Extensible to organizations SOPs
- Runs test code and captures results



```
valtools::vt_use_report()
```

Validation Report

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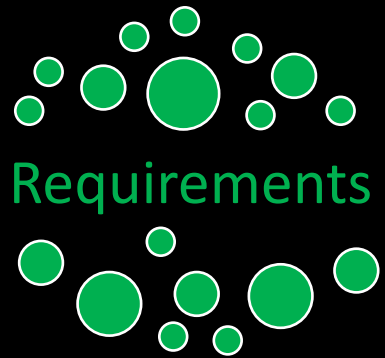
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PUSH BUTTON GET VALIDATED

Validating the Package

`vt_validate_source()`

Execute validation report on release for package build using this framework

`vt_validate_install()`

Execute validation report on installation for package build using this framework

`vt_validate_installed_package()`

Execute validation report on update of system environment on package build using framework

Validation
+ R
4ever

Thank You PHUSE US CONNECT

The creation of this framework would not have been possible without the support of my team at the Hutch, the PHUSE R Package Validation Working Group, and numerous contributions to the open-source tools this framework is dependent on.

