



Git-based workflow for R package validation

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July 8, 2026, UseR!2026

The use of R packages in a regulated environment, as in pharmaceutical companies, might require a formal validation of internal R package. This ensures that the functional testing procedure for such software package is documented as mandated by the ICH E9 guideline¹.

We will contribute to this effort by presenting a git-based lightweight workflow to automate the creation of validation form with the **pkgTesteR**² (and **packamon**³) R packages. This workflow has been successfully applied for the validation of R packages creating interactive Tables Figures and Listings (TLFs) for clinical data review⁴.

PROCESS

The entire process (besides reviewer approval) is executed in an automated workflow via a CI/CD tool.

Development phase

Based on user requirements:

- The R developer creates a R package dedicated to an application.
- The source code is tracked in a git repository.
- All the functionalities are tested by unit tests included in the R package.

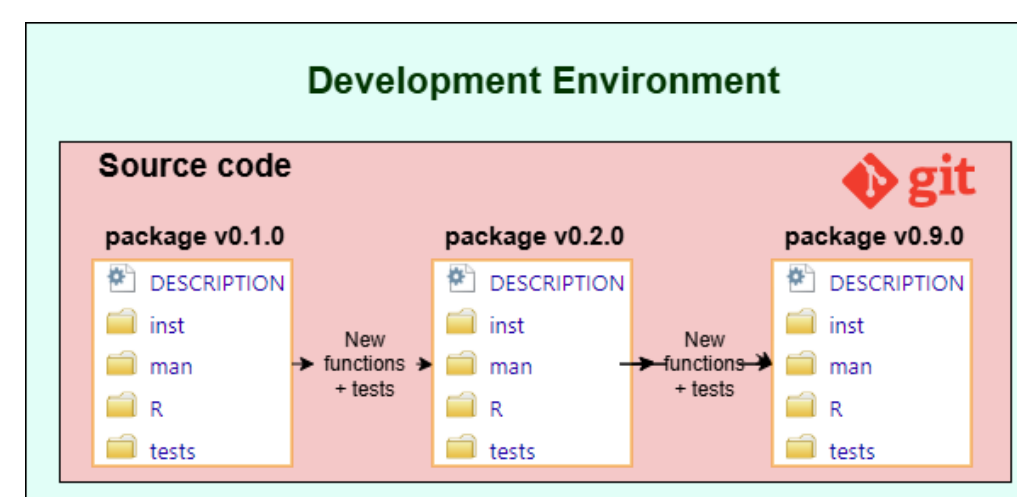


Figure 1: Development phase

Production phase

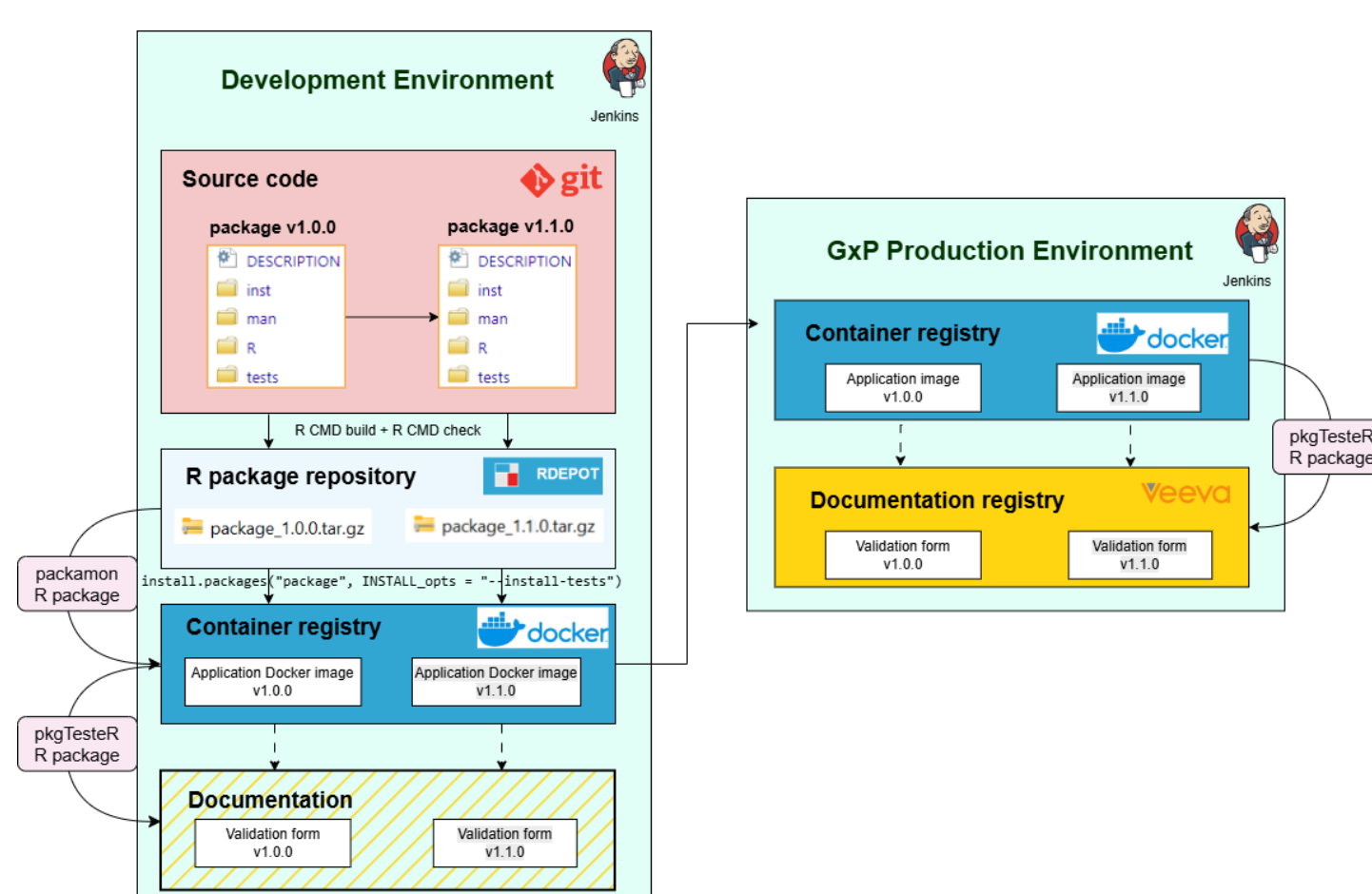


Figure 2: Production phase

Once the package is ready to be deployed into production:

- Its version is labelled with a git tag.
- After successful built/check, the R package is uploaded to the repository.
- An 'application image' is created with the R package (installed with its tests) and all its (R and external) dependencies.
- The 'application image' is moved from the development to production container registry.
- A validation form is created for the R package installed inside the 'application image'.
- The validation form is reviewed and approved by an external reviewer (e.g. business user) and stored in a GxP documentation registry.

VALIDATION FORM

Environment

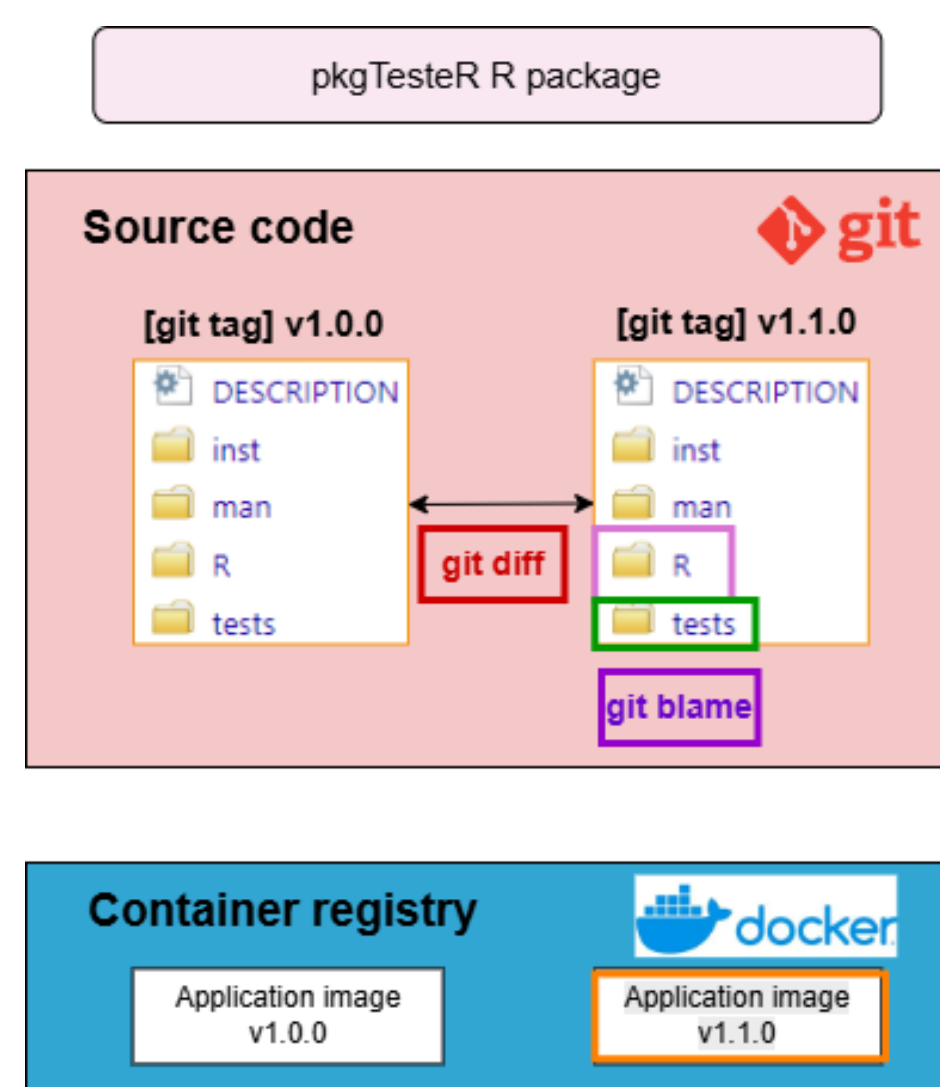


Figure 3: Components used for the creation of the validation form

Test results

Summary					
Number of UR and tests that passed, failed or completed with warning(s)					
Type	Total	Passed	Warning	Failed	Skipped
Tests	932	838	82	12	0
UR	458	415	40	5	0

Figure 4: Summary of test results

UR tested	Context	File name	Test description	Number of tests	Passed	Failed	Warning	Skipped	Real time
UR-n-1	Combine summary statistics tables	test_combine.R	An error is generated if summary tables without variable names are combined	1	1	0	0	0	0.02
UR-n-9	Create a subject profile summary plot with aesthetics	test_subjectProfileSummaryPlot.R	Points are correctly labelled with a text justified based on data variables	2	0	0	2	0	0.15
UR-n-2	Export summary statistics table to a flextable	test_exportSummaryStatisticsTable.R	A cell is correctly formatted with multiple and different text formatting in a flextable summary table	3	0	3	0	0	0.11

Figure 5: Test results by User Requirement

Detailed results for failed tests	
Type: failure	A cell is correctly formatted with multiple and different text formatting in a flextable summary table
Expectation 1:	Expected cntData[, "text"] to equal c("test", "c.0.001"). Differences: target is NULL, current is character
Type: warning	Points are correctly labelled with a text justified based on data variables
Expectation 1:	No shared levels found between names (values) of the manual scale and the data's linetype values.

Figure 6: Errors and warnings

UR ID and new tests

UR ID	Requirements	Test File
UR-k-1	Format numbers: An error is generated if neither a rule or data are specified for the extraction of the number of decimals	test_decimals.R
UR-l-1	Export summary statistics table as data frame: The summary table is correctly exported to a text file in base format as specified	test_exportSummaryStatisticsTable-df.R
UR-l-2	Export summary statistics table as data frame: The summary table is correctly exported to a text file in base format by default	test_exportSummaryStatisticsTable-df.R
UR-l-3	Export summary statistics table as data frame: The summary table is correctly exported to a text file in in-text format as specified	test_exportSummaryStatisticsTable-df.R
UR-l-4	Export summary statistics table as data frame: A list of summary tables is successfully exported to text files in base format	test_exportSummaryStatisticsTable-df.R
UR-l-5	Export summary statistics table as data frame: A list of summary tables is successfully exported to text files in in-text format	test_exportSummaryStatisticsTable-df.R

Figure 7: User Requirement ID

New tests		
8 new tests are included in the version 3.3.0 of the inTextSummaryTable of the package. These tests are highlighted in bold and italic in section 'User requirements'.		
UR ID	test	file
UR-l-4	A list of summary tables is successfully exported to text files in base format	test_exportSummaryStatisticsTable-df.R
UR-l-5	A list of summary tables is successfully exported to text files in in-text format	test_exportSummaryStatisticsTable-df.R
UR-n-67	A summary table is correctly exported to a doc file in landscape format without additional empty pages	test_exportSummaryStatisticsTable-flextable.R
UR-n-68	Column headers of a summary table are not merged if specified	test_exportSummaryStatisticsTable-flextable.R
UR-n-69	Column headers of a summary table with identical elements across consecutive columns and rows are correctly merged	test_exportSummaryStatisticsTable-flextable.R
UR-n-70	Column headers of a summary table with identical elements across consecutive columns or rows are correctly merged	test_exportSummaryStatisticsTable-flextable.R
UR-x-11	Extra ggplot specified as a function is correctly included	test_subjectProfileSummaryPlot-general.R
UR-x-12	Extra ggplot with a data point outside the plot range is correctly included	test_subjectProfileSummaryPlot-general.R

Figure 8: New tests

Test script

Verification approach			
Function	Risk Level	Minimum verification approach	Test File
exportSummaryStatisticsTable	high	Formal testing as described will be done	test_exportSummaryStatisticsTable-df.R, test_exportSummaryStatisticsTable-OT.R, test_exportSummaryStatisticsTable-flextable.R
formatPercentage	high	Formal testing as described will be done	test_decimals.R, test_getStats.R
geomCV	high	Formal testing as described will be done	test_stats_utility.R
geomMean	high	Formal testing as described will be done	test_stats_utility.R
geomSD	high	Formal testing as described will be done	test_stats_utility.R

Figure 9: Functionality <-> Test script

Test script	
The source code of the tests is available below.	
<pre>library(testthat); library(inTextSummaryTable) File: test_exportSummaryStatisticsTable-df.R context("Export summary statistics table as data frame") test_that("A list of summary tables is successfully exported to text files in base format", { summaryTables <- list(A = data.frame(PARAM = "A", n = 10), B = data.frame(PARAM = "B", n = 9)) file <- tempfile(pattern = "table", fileext = ".txt") ft <- exportSummaryStatisticsTable(summaryTable = summaryTables, rowVar = "PARAM", statsVar = "n", file = c("data.frame-base" = file)) for(i in seq_along(summaryTables)){ expect_equal(object = read.table(file = paste0(" ", i, ".txt"), header = TRUE, sep = "\t"), expected = summaryTables[[i]]) } })</pre>	

Figure 10: Test script

ACKNOWLEDGEMENTS

- Open Analytics packamon team
- R community: authors of the **git2r**, **testthat**, **flextable**, **officer**, **rmarkdown**, **valtools** R packages

¹ICH E9 Statistical Principles for Clinical Trials Guideline, Food and Drug Administration, 1998, <https://www.ich.org/page/efficacy-guidelines>

²pkgTesteR: <https://github.com/openanalytics/pkgTesteR.git>

³packamon: <https://repos.openanalytics.eu/public>

⁴Interactive medical and safety monitoring in clinical trials with clinDataReview: a validated and open-source reporting tool, Cougnaud et al., Frontiers in Medicine, 2024