

Risk-assessment of R packages in a Biopharmaceutical Regulatory Setting.

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Abstract Text:

This contribution reflects on framework and tools by the R Validation Hub for risk-based assessment of R packages within validated infrastructure.

The R Validation Hub is a cross-industry initiative, led by approximately 10 organizations with frequent involvement from health authorities. The R validation Hub is funded by the R Consortium and has the mission to support the adoption of R within regulated industries, with an emphasis on biopharmaceuticals.

We will discuss the framework for the risk-based assessment of R packages, that has been utilized by key pharma companies across the industry. We will also showcase the {riskmetric} R package, that evaluates the risk of an R package using a specified set of metrics and validation criteria, and the {riskassessment} app, that augments the utility of the {riskmetric} package with a Shiny app front end. Lastly, we will outline a prototype of a technical framework for a 'repository' of R packages with accompanying evidence of their quality and the assessment criteria.

Keywords:

R Package|Risk assessment |Open-source software|Regulated environment|validation|

Additional Information: Submission Details

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