

Title:

R Validation Hub: A Shiny App for R-Package Risk Assessment

Abstract:

From the R Validation Hub, the {riskassessment} app enhances the utility of the popular {riskmetric} package. That is, it provides a helpful shiny interface to assess the risk of using a CRAN or Bioconductor R package in regulated environments. The app's methods align with the push towards risk-based computer system validation, guiding organizations to identify, measure, and make decisions regarding potential risks. Beyond risk assessment, the app offers tools for tracking metrics and quantitative risk scores over time, introduces optional decision automation, plus compiles user comments & summaries from the entire review process to generate detailed reports for regulatory authorities. This work exemplifies the R Validation Hub's mission to foster reproducible validation efforts in our industry, promoting responsible usage of R for clinical trials.