Developing a Risk-based Approach for Assessing R Package Accuracy

Authors (affiliations):

Juliane Manitz (EMD Serono), Doug Kelkhoff (Roche/Genentech), Yilong Zhang (MSD), Lyn Taylor (Phastar), Joe Rickert (R Consortium), Min Lee (Amgen), Keaven Anderson (MSD), Andy Nicholls (GSK)

On Behalf of the R Validation Hub, an R Consortium-funded ISC Working Group

Abstract (<1200 characters):

This contribution has the aim to discuss possible risk-based approaches to assess R package accuracy within a validated infrastructure. Ideas and suggestions reflect current thinking of the R Validation Hub working group, which is a cross-industry initiative funded by the R Consortium. Our mission is to enable the use of R by the bio-pharmaceutical industry in a regulatory setting, where the output may be used in submissions to regulatory agencies. In this setting, R is required to be part of a validated system, which encompasses software accuracy, reproducibility and traceability. We differentiate two types of R packages: Core and recommended packages are shipped with the basic installation. A rigorous software development lifecycle assures minimal risk. However, contributed packages may vary in their accuracy and development rigor, which could be assessed by various metrics. This cross-industry WG suggested several relevant quality metrics, and is developing an R package that provides a workflow to evaluate the quality of a set of R packages. This work may also be relevant in other regulated areas such as financial service industries and agriculture.

Additional Information:

Type of presentation: regular talk

Primary area: reproducibility

Keywords (2-3): Validation, risk assessment

Website: www.pharmaR.org

GitHub Organization: https://github.com/pharmaR

Technical report: https://github.com/pharmaR/white_paper

This topic has been previously presented at R/Pharma, however this work may also be relevant in other regulated areas such as financial service industries.