Validation Hub

Why invest in the Regulatory R Repository

As our industry looks for ways to lower costs and shorten regulatory review processes, there has been a move to investigate and employ the R statistical programming language for broader use in clinical research and drug submissions. While quickly accomplishing the goal of lowering internal software and hardware costs, there are still some hurdles to overcome in this transition to broader use of open source across the pharmaceutical industry.

As companies move to deliver more R-based submissions an industry-wide effort is needed to standardize package validation for submissions to our government agency partners. A consistent and publicly available repository of risk-assessed packages will allow our agency partners to develop familiarity and trust, allowing for submissions to be processed faster and with a high level of confidence. To cement cost savings and speed up agency review of R-based submission packages, we are proposing the development and maintenance of the Regulatory R Repository.

The Regulatory R Repository will provide a collection of assessed R packages utilizing **the R Validation Hub's riskmetric framework**. The framework allows the user to quantify package quality and provide transparent, risk-based decision-making for regulatory use cases. This repository will eliminate the need for pharmaceutical companies, large and small, to spend time and money investigating packages and performing their own evaluations. Instead, the repository will allow companies to select packages based upon their own risk profile from a public repository of risk-assessed R packages that meet regulatory requirements for pharmaceutical submissions.

How to help build and maintain the Regulatory R Repository

We need funding partners to help us raise $250,000 USD to build the first version of the R Regulatory Repository. A grant or donation through the **R Consortium**, where our working group is maintained, will allow us to hire contractors to do the testing and publishing of our first set of packages.

If you or someone you know in your organization would like to help fund this work, please visit our project landing page, review our materials, and opt-in to our mailing list as either a potential sponsor, project champion, or project contributor.