

The R Validation Hub

Mission statement

- *R Validation Hub is a cross-industry initiative whose 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.*
- Our platform will always be free to use!

Prior to 2018

- Companies working in isolation to validate/qualify environments using R
- Else purchasing a validated R system from a software provider

May 2018



- PSI AIMS SIG tasked by PSI Board to investigate use of R in Pharma
- AIMS awarded R Consortium ISC funding for “Collaboration to create online R package validation repository”
- Initial website now Live - Lots more to do!!

<https://www.pharmar.org/>

More detail: <https://www.r-consortium.org/announcement/2018/05/29/announcing-the-r-consortium-isc-funded-project-grant-recipients-for-spring-2018>

Who are we?

- Executive Committee
 - Andy Nicholls (AIMS)
 - Lyn Taylor (AIMS)
 - Joe Rickert (R Consortium)
 - Min Lee (Transcelerate)
 - Yilong Zhang (Metrics stream)
 - Keaven Anderson (Testing stream)
- Over 30 pharmaceutical organisations represented

Where are we?

- Focus thus far on:
 - Provision of website - the 'Information Hub'
 - Development of R package for simplified collection of risk metrics
- Future plans
 - Continue to develop website
 - Share set of standard qualification tests
 - Become a forum for statistical discussion
 - Create a pharmaceutical repository of 'accepted' packages

Questions?

