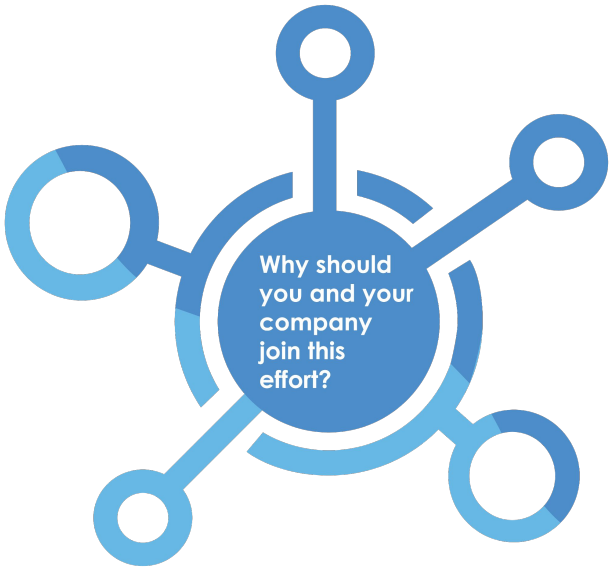
Reg R Repo working group

Validation Hub

Our vision

Using R in submissions to healthcare regulators is challenging.

This working group strives to identify and prototype a transparent, open, dynamic, cross-industry approach of establishing and maintaining a 'repository' of R packages with accompanying evidence of their quality and the assessment criteria, that can be used to simplify necessary in-house validation processes as much as possible.
Such a cross-industry 'repository' could help with burden-sharing of validation efforts, improve quality via transparent, open peer review, and de-risk the use of public R packages for regulatory submissions.



Becoming a part of our working group provides invaluable insights from cross-industry and regulators for companies considering the transition to using R for regulatory submissions. By participating in this collaborative effort, you will be better equipped to make informed decisions, to accurately gauge when the R ecosystem has reached the necessary maturity level to meet your company's quality standards and culture of smart risk-taking.

Benefits of joining the working group also include:

- Insider info of what other orgs are doing/thinking in this space
- Positive visibility for participating organizations showing commitment to open-source solutions
- Ability to influence final solution to ensure compliance with existing internal solutions
- Future state - reduced cost and effort of maintaining internal or purchasing vendor solutions for qualified R packages
- Your personal development:
    - Help to co-create a solution including CI/CD pipeline automation, frontend and backend development
    - Be a part of a highly differs and international team consisting of multiple pharma companies and regulatory authorities

Time commitment

10% full time equivalent.

Know more