



Regulatory Repos WG

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Who we are

- (Predominantly) Pharma industry participants advocating for use of R
- Focus on hurdles regarding regulatory compliance in choice of software
- Providing tools, process recommendations for in-house solutions

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- Working toward a public solution that is driven by our guidelines
- Collecting needs from industry participants and health authorities

Challenges

- Guidelines often still lean on judgement calls:
 - statistical robustness
 - in-house statistical domain experts reviewing methods
 - appraisal of maintainer reliability
- Understanding the need
 - Prior efforts focused on known gaps (translation of process for vendored solutions)
 - Using repo group to re-investigate industry needs

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Current Range of Proposed Solutions

DIY Tools

Provide tooling for validated package cohort management

Curated Universe

A collectively managed listing of regulatory-ready packages

Public Repo

Embed needs within a public package repository

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Key Learnings so Far

Industry Validation Leads

- Some prefer direct visibility of open source code, reducing need for vendor audits

Health Authorities

- Primary concern is security vulnerabilities
- Health authorities seem to be *mostly* satisfied with statistical trust
note: definite industry selection bias toward “low risk” stats packages

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Next Steps

- Wireframing solutions
- Going back to stakeholders for feedback with wireframe demos

R Consortium Repos WG Crossover

- We're still finding our best path, and might not settle on a hosted repo
- We'd love to be connected, especially if our needs end up generally useful
- At the least, we'd like to be a requirements gathering arm for the R ecosystem at large to help translate pharma needs