

PHUSE APAC CONNECT 2026 ET12

ValoRpacks – self-service R package validation

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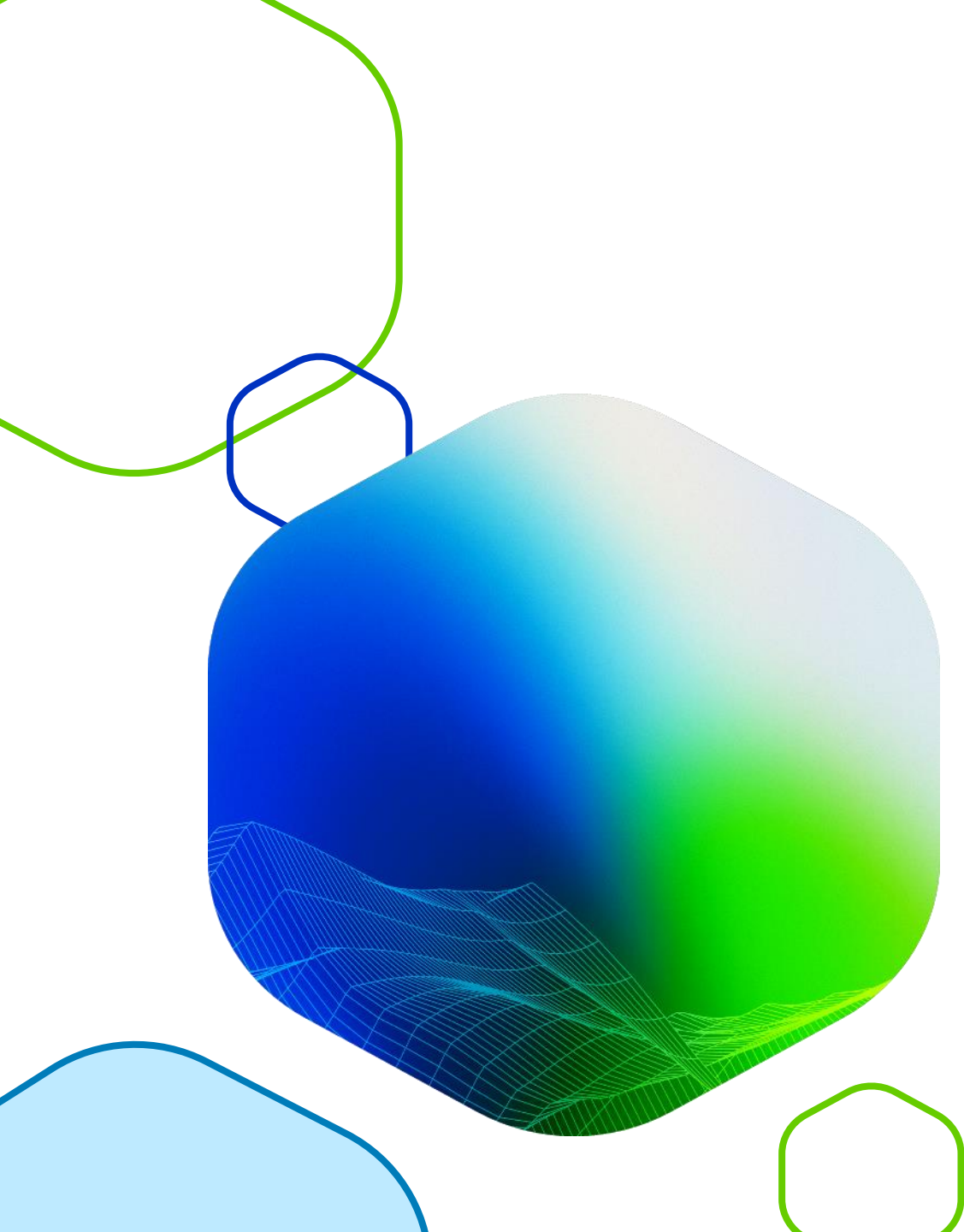
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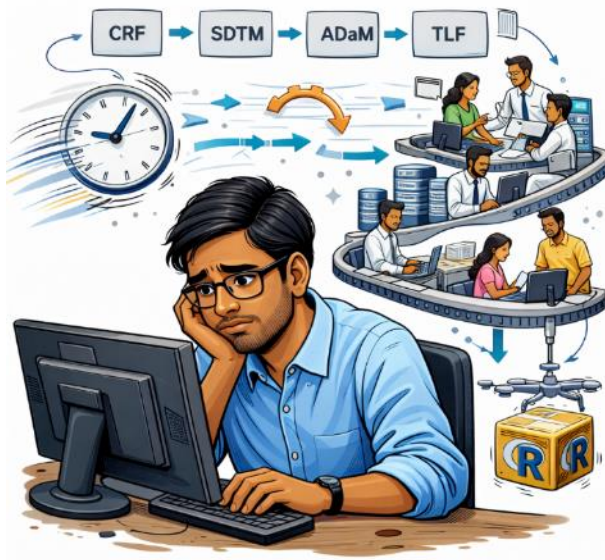
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Agenda

- Motivation
- ValoRpacks framework
- Comparison with alternatives
- Conclusion and outlook

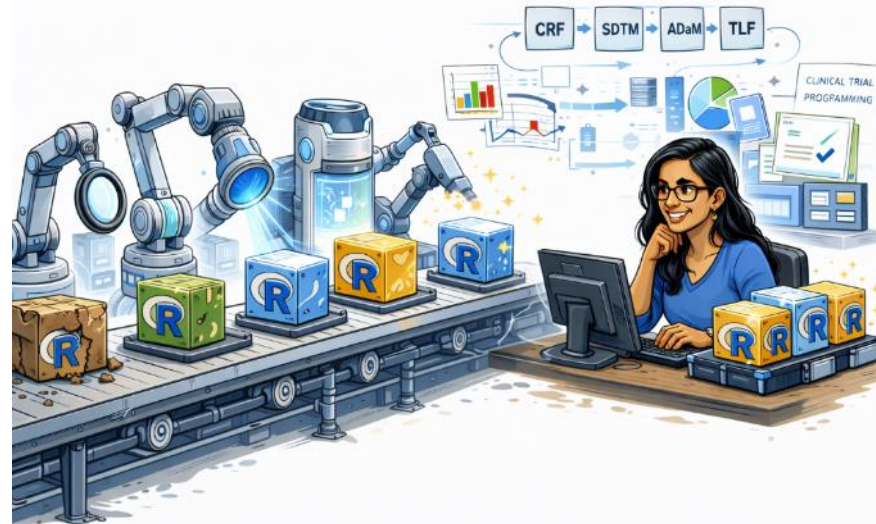
Motivation



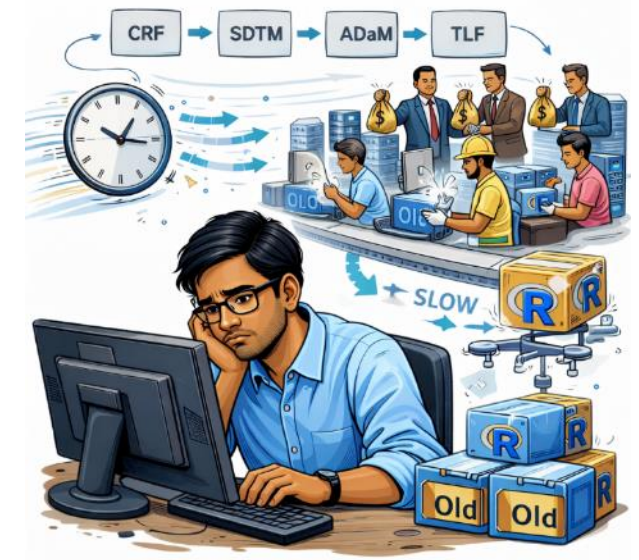
Proprietary Process



Exploratory Research

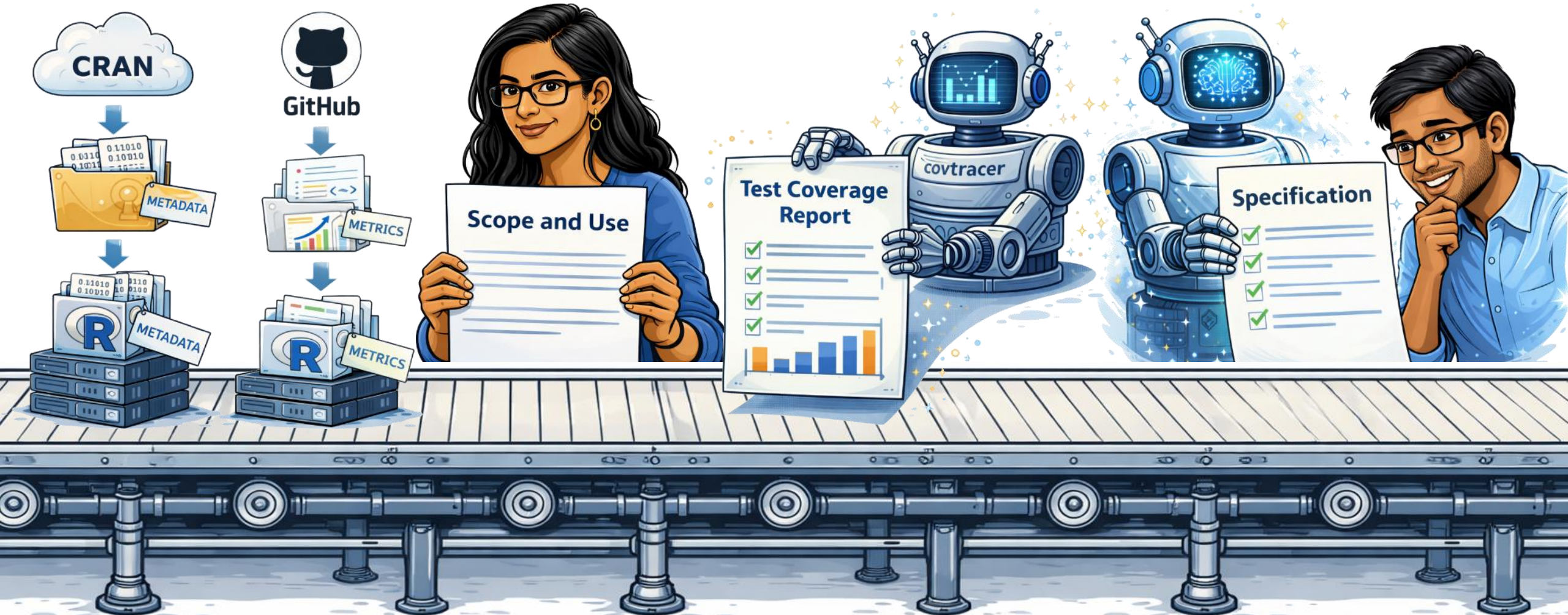


ValoRpacks

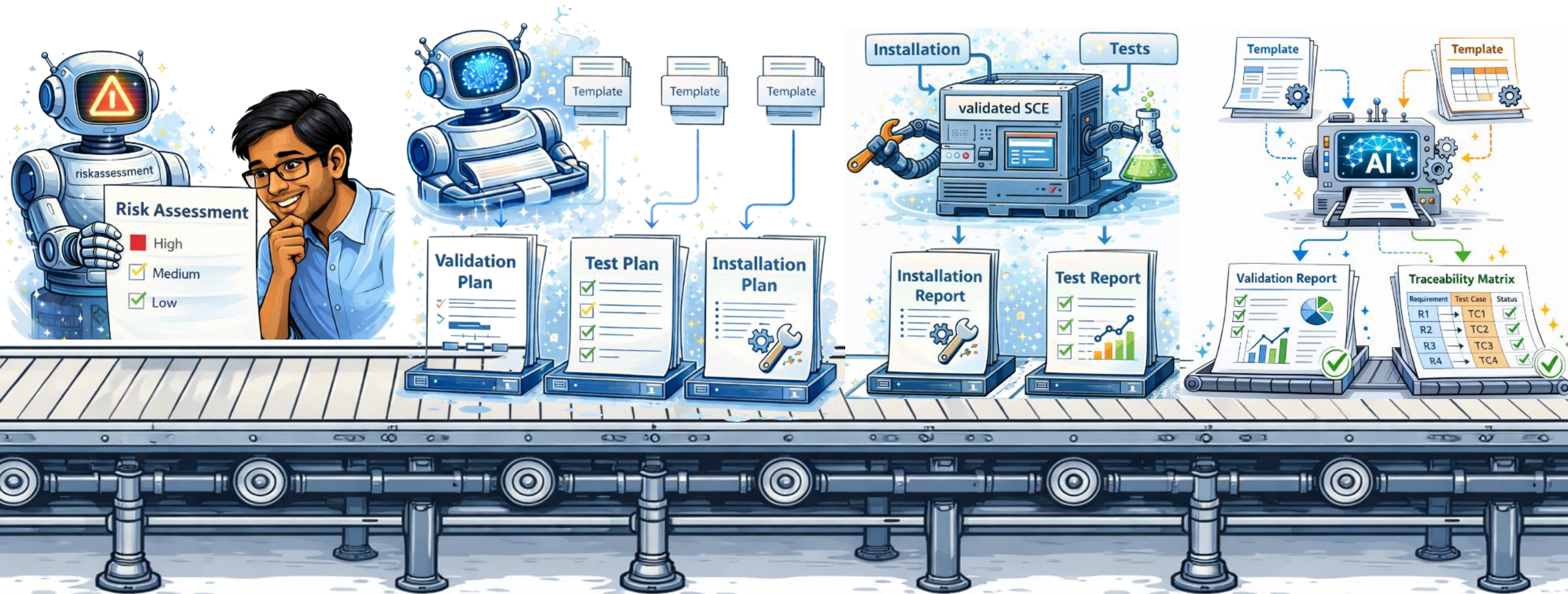


Commercial Provider

ValoRpacks Framework



ValoRpacks Framework



ValoRpacks Framework



Comparison with alternatives

Aspect	ValoRpacks	Proprietary framework	Commercial provider
GxP compliant R package validation	✓	✓	✓
Automated process & low human effort	✓ by the use of of automation and AI	✗ manual validation	✗ not relevant
Latest package versions available	✓ enabled by short validation cycles	✓ if supported by the framework	✗ provider controls availability
Embedded in SCE	✓ natively in FastTrack others as extension	✗ not in commercial SCEs	✗ not available
Support of larger package sets	✓ no additional cost	✓ with additional cost	✓ with additional cost
Support of multiple package versions	✓ no additional cost	✓ with additional cost	✓ with additional cost
Long term maintenance and support	✓ by entimo	✗ not considered	✓ by provider

Conclusion and outlook

- ✓ Increasing R adoption in regulatory contexts
- ✓ Clear guidelines on R validation available
- ✓ Useful tools available
- ✗ No holistic self-service framework available
- ✓ ValoRpacks closes this gap

 Reach out to entimo to learn more

References

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- (4) <https://posit.co/webinar/novo-nordisk-journey-to-an-r-based-fda-submission/>
- (5) <https://r-consortium.org/posts/johnson-and-johnsons-success-story-a-hybrid-r-sas-strategy-for-fda-submission/>
- (6) <https://pharmar.org/riskassessment/>
- (7) <https://github.com/genentech/covtracer>
- (8) <https://testthat.r-lib.org/>
- (9) <https://pharmar.org/white-paper/>
- (10) <https://github.com/uptake/pkgnet>
- (11) <https://pkgdown.r-lib.org/>
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Thank you! Questions?



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