

Modernization of Statistical Analysis (MSA) Framework provides principles for demonstrating in increasingly complex Case Studies that software, including nontraditional, is reliable & robust.

Accuracy

- Validation of task-specific packages and algorithms, non-traditional software

Reproducibility

- Nontraditional package management

Traceability

- Automate generation of task-specific code
- Risk-based software qualification

Accuracy

- Risk-based software qualification
- Modular software development & qualification

Reproducibility

- Dedicated, controlled and qualified environment for production results

Traceability

- Log contextual information at runtime

Accuracy

- Test / validation automation

Reproducibility

- Management & maintenance of longitudinal analytics environments
- Transition uncontrolled exploratory analyses to production environment

Traceability

- DevOps tools
- Continuous integration & dev, CI/CD, pipelines

Accuracy

- Submission of results and documentation to health authorities

Reproducibility

- Containerization of reproducible environments

Traceability

- Integration with clinical data repository
- Track and bundle contextual records of analyses

Accuracy

- Static and interactive reporting and visualization
- Industry collaborative data exploration with reproducible and traceable analysis and reporting
- Foundation packages for regulatory reporting

Reproducibility

- Code available to document interactive data displays

Traceability

- Containerization and records of contextual details

Sponsors report that the MSA Framework facilitates success with increasingly complex initiatives.

Challenge: Manage and **mitigate** risks of volatile software libraries.

Solution: Collaborative groups of **cross-functional experts** from business, IT & quality. Establish processes and practices to de-risk libraries & balance the **burden of validation**. Manage complexity, maximize **confidence** & balance the **burden of review**.

Accuracy

Measure of **correctness** and **consistency** of **software libraries** in the context of use.



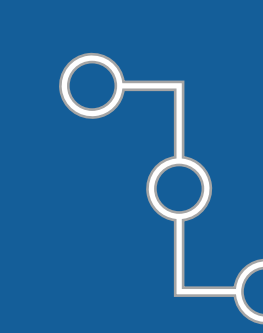
Reproducibility

Ability to **reliably reproduce** derived results from original code, libraries, configs and inputs.



Traceability

Ability to **trace** derived results through **environment** and **algorithms**, back to **original inputs**.



The MSA Framework is built on a foundation of the ART model to establish Accuracy, Reproducibility, and Traceability.