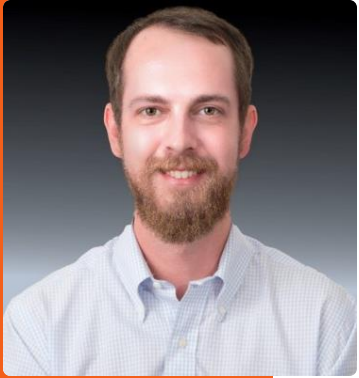


A TransCelerate Initiative: Paving the Way for the Adoption of Modernized Statistical Analytics

TransCelerate Modernization of Statistical Analytics (MoA) Initiative

March 2023



Speaker

Nicholas Masel

TransCelerate

- MoA Team Member

Johnson & Johnson

- Associate Director Innovation Team Lead

A Member-Driven Mission

Our Members are passionate about designing solutions to address R&D's most complex challenges related to clinical development & drug safety.

Membership is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines*



* to be eligible for membership, companies must meet specified eligibility criteria.
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Objectives of Modernization of Statistical Analytics (MoA) Initiative

The Current Landscape



Limited Regulatory Guidance

Specific analytical software is not required, but today's limited guidances create a significant obstacle to adopting new analytical tools



Increasing data volume

Emergence of electronic and digital data sources in clinical research has created a need for more advanced analytical capabilities



Greater availability of advanced technology

There are more advanced analytic capabilities that could be customized as fit for purpose in R&D

The Need

Organizations need to find a way to demonstrate to regulatory agencies that any analytical solution produces **credible results** and are suitable for use in the regulatory process.

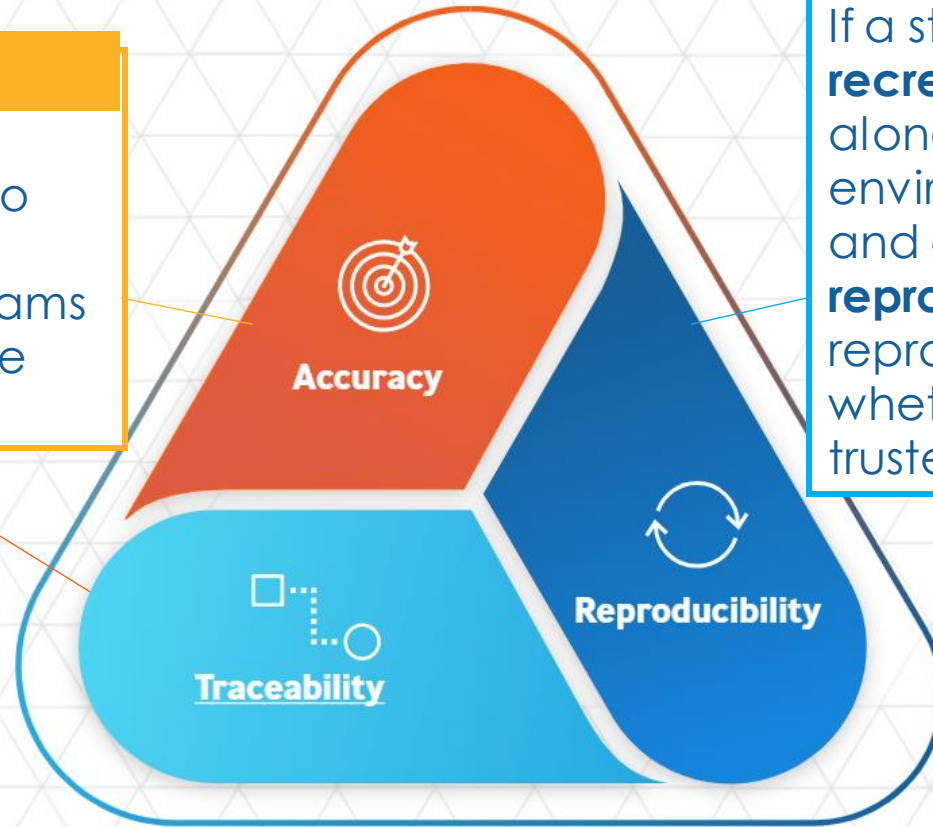
Three Core Principles for Regulatory Compliance & Implementation Success

Accuracy

The measure of **correctness** of *software* libraries that are used to generate results from an MSA environment – it is not the programs that developers write using those software libraries.

Traceability

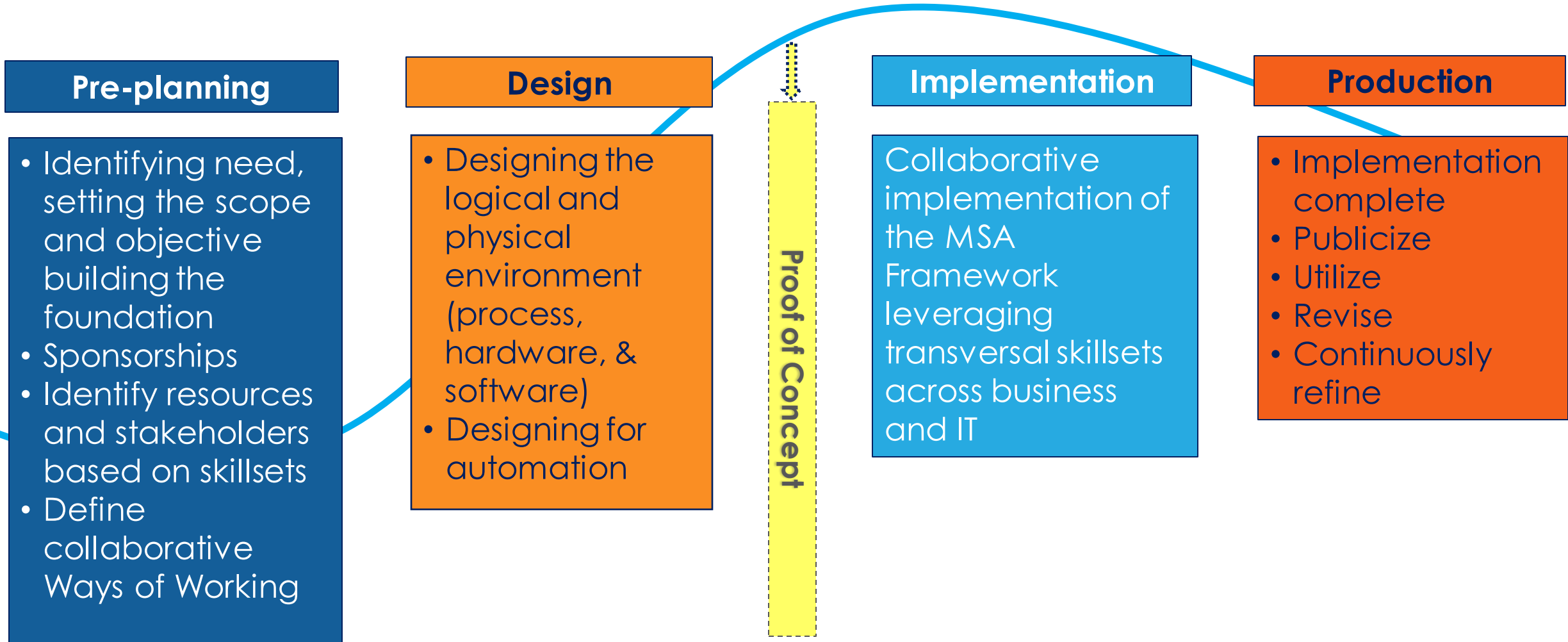
Refers to the ability to **trace inputs to outputs**, with the main goal being to provide evidence to connect e-data, code, and environment to the final output that is produced.



Reproducibility

If a statistical analysis output can be **recreated from the original dataset** along with the associated environment, including all artifacts and dependencies, it is **reproducible**. If an output is not reproducible, it is questionable whether results of the output can be trusted.

Implementation Model Of The MSA Framework



MoA Case Studies

#1: Using open-source tools to develop interactive displays to facilitate internal and regulatory review

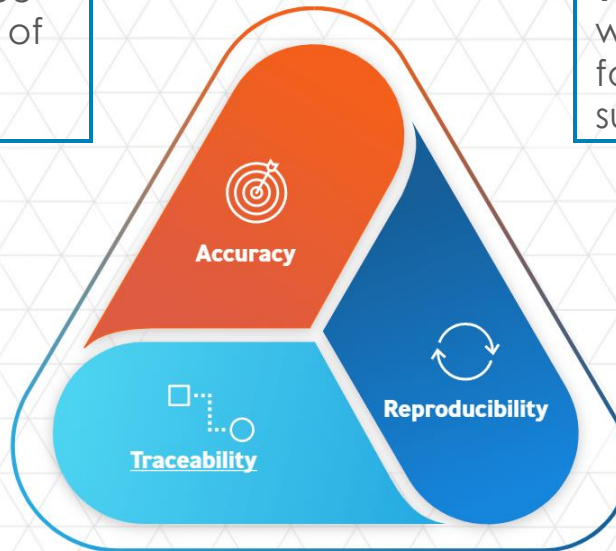
Why MSA: Quality and GxP compliance of dynamic visualizations means ease of use and increased confidence of reviewers.

#2: Different open-source installations for exploratory and regulated work in the same computational environment

Why MSA: Greater control and confidence in submission work and ability to apply traditional independent QC process.

#3: Using open-source tools to automate group sequential designs of clinical trials

Why MSA: Robust testing and automated code/report generations improve GxP compliance as updates are made to statistical tools for adaptive study designs.



#4: Provision of a single environment for both exploratory and submission related analyses using open-source products

Why MSA: Risk-based validation along with continuous integration/development forged a path from exploratory to submission.

#5: A new non-traditional statistical analytic environment with commercial validated solutions for regulated work

Why MSA: Establishing standard processes with controlled updates and IT support enabled digital transformation while retaining/attracting talent.

#6: Fit-for-purpose package assessment and GxP validation for both exploratory and submission work

Why MSA: Risk-based approach to testing and validation delivers higher quality and confidence with greater efficiencies.

Risks, solutions, and MoA Framework components

Tips to design and document deployments

Case Study Risk	Sponsor Solution	MoA Framework Components and Principles
#1 Interactive analysis platform, open-source		
Validation of non-trad code	Modular approach	Risk-based assessment framework for non-traditional tools
Confidence in platform	Open-source packages	Governance, Process & Tools
#2 Environment for Regulator Submission		
Validation, non-trad pkgs	Qualification → Verification	Confidence / Impact framework
Flexible access to open-source code packages	Separate exploratory & submission software envs	Intended use / Impact framework
#3 Group Sequential Design application		
Reliability of complex code	Plan, execute & doc SDLC	Risk-based verification framework
Reproducibility	Automate documentation of software environment	Reproducibility framework

2023 & Beyond Focus

Build confidence with **Health Authorities:**

- **MoA Framework** can de-risk technology initiatives.
- Software & technology advances conducted, documented, & presented according to the MoA Framework can facilitate review and regulatory decision-making.





Engage With Us

- ▼ Careers
- ▼ Have an Idea? Let Us Know!
- ▼ Give Feedback to an Initiative
- ▼ Share Your Implementation Experience
- ▼ Join Our Awareness & Implementation Community
- ▼ Contact Us



Engage With Us - TransCelerate
(transceleratebiopharmainc.com)

Global Headquarters

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We'd love to hear from you!

**Share feedback, comments
or request more information
using our MoA "Engage with
Us Form".**



Give Feedback to an Initiative



Some of our initiatives are currently seeking feedback. If you have interest in providing input please select the initiative name from the dropdown below to complete their information request form. Please provide your email if you require a response to your inquiry. TransCelerate cannot respond through the feedback forms.

Initiative: **Modernization of Statistical Analytics** ▼

Modernization of Statistical Analytics Feedback Form

TRANSCCELERATE INVITES YOU TO COMMENT ON THE MODERNIZATION OF STATISTICAL ANALYTICS (MSA) FRAMEWORK. PLEASE SHARE YOUR THOUGHTS AND RECOMMENDATIONS ON THIS SOLUTION PROPOSED BY TRANSCCELERATE.

NAME *

THANK YOU

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