

Expanding the Toolbox & Socializing the Solutions...

An Application of TransCelerate's MSA Framework for Assessing Accuracy, Reproducibility, and Traceability in Novel Software Implementations
in a way that IT, QA, and Management will embrace.

TIM KUHN

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Welcome



Tim Kuhn

- Health Authority Sub Team Lead, TransCelerate Modernization of Statistical Analytics
- Associate Director, R&D Quality Assurance, AbbVie





TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

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*

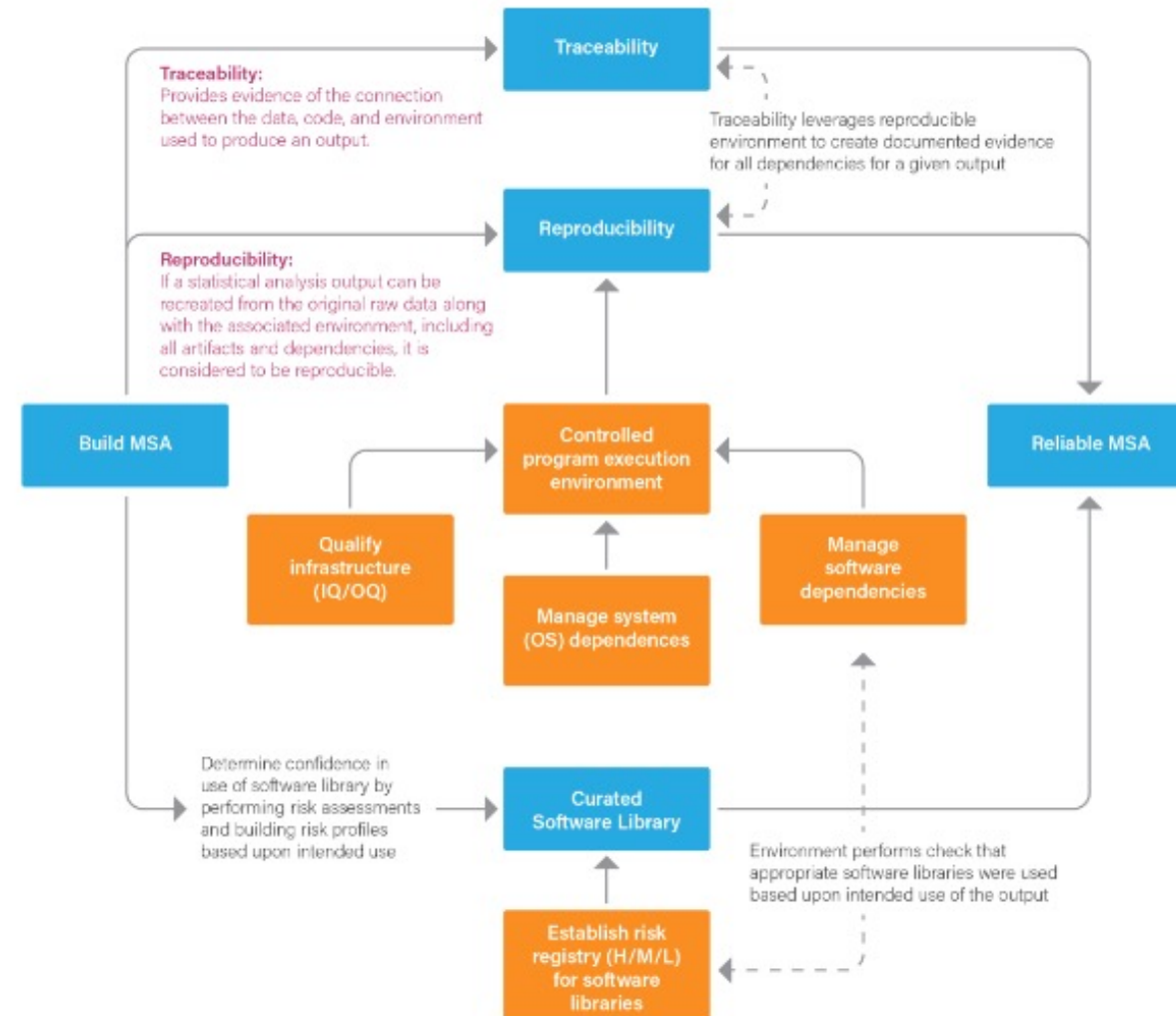


* to be eligible for membership, companies must meet specified eligibility criteria.



What is the MSA Framework?

We want to use these tools....how do we make using them ok?



More Advanced Statistical Analytical Tools Could Greatly Facilitate & Expedite Clinical Research & Development

Such tools already exist to tackle today's challenges, but they must meet Health Authority expectations

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 (automation, machine learning algorithms, etc.) 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.



The Potential Benefits of Establishing a Modernized Analytics Environment

Modernization of Analytics Benefits

Streamlined Regulatory Submission Process



Improved Data Analysis & Decision Making Process



Cost Efficiency with Organizational Implementation



Recruit, and retain top talent



Applicable Areas

Regulatory Reporting

Biostatistics

Statistical and Clinical Programming

Information Technology

Process Improvement

Human Resources

Outcome/Risks

Improve speed of overall Healthcare Delivery



*MCPMod/DoseFinding
COVID-19
RTOR*

The Modernization of Statistical Analytics (MoA) Initiative

An approach for demonstrating to Health Authorities the reliability of analytical software

Framework Objective

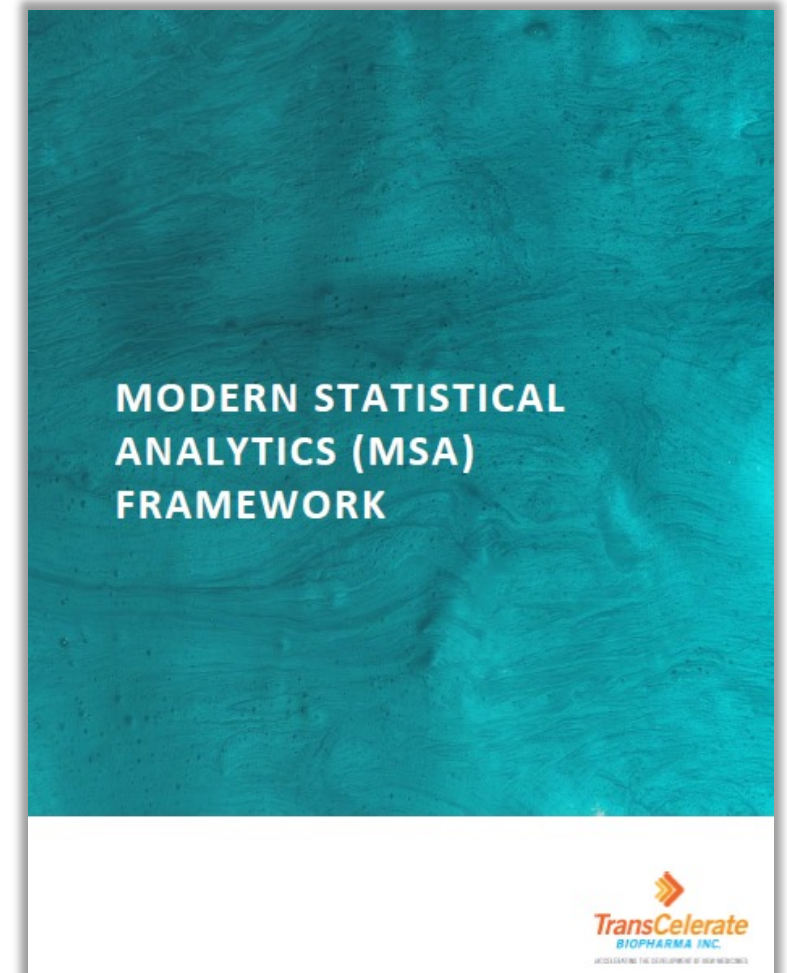
Provide practical guidance on how to approach regulatory agencies in an effort to demonstrate to them that any analytical solution produces credible results and are suitable for use in the regulatory process.

Methodology

Based upon a methodology that establishes the principles of **Accuracy**, **Reproducibility**, and **Traceability** for a modern analytical software environment to demonstrate that results it generates is **reliable**.

Practical Guidance

Best practices and guiding principles are also provided to support the Framework's implementation across industry sponsors and other stakeholders.



Who is Tim really?

Inspections

Role of
Validation
QA

Independent

Audits

NO!



The Framework is a beginning....

Beyond Academics



Health Authority Engagement

Approvals



How do we make
this a reality?



Politics



Speed Bumps and Barriers



- Precedents
- Perceptions
- People
- Policies
- Politics
- Power



Practical Considerations for Implementations

Sphere of Control, of Influence



Stakeholders

Accepting calculated risks

Biostatisticians

Biostatisticians will work together with statistical/clinical programmers to vet and define which new analytical tools will be added to the environment



Statistical/Clinical Programmers

Programmers will work together with biostatisticians to vet new software but also carry out specific validation efforts as it relates to specific use of new software



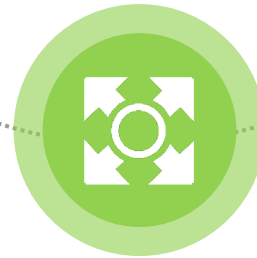
Quality Assurance

Quality SMEs will provide regulatory oversight in guaranteeing the tools remain compliant for use



Information Technology

IT will take Commercial-off-the-shelf (COTS) solutions and install them into the server environments. They will work closely with engineering to develop streamlined or automated processes for these deployments



*Many roles will need
to come together to
achieve vision*

External Partners

External partners such as CROs will deliver on the Sponsor Companies' future analytical needs



Things to do



Talk with stakeholders

Plan for more work up front



Proceduralize

Establish proof of concept



Code approval track

Talk with Regulators



Check in/Check out

Document progress, wins, missteps



Discussion on risk

Stay people centric



Start small



Point at the MSA Framework Directly



01

Cite this work in charter documents

02

Discuss these ideas with Management

03

Connect with the current TransCelerate MSA Framework

04

Provide your feedback directly on the MSA Framework to TransCelerate



Point at the Use Cases

- ☐ Library risk assessment
- ☐ Machine Learning
- ☐ Modern computing environment
- ☐ Advanced statistical methods
- ☐ Interactive visualizations
- ☐ Automated reporting
- ☐ Software Delivery Life Cycle (SDLC) / Testing / Reproducibility



Specific Use Case Summary



- PHUSE Canton (9/2020)
- PHUSE Chennai (10/2020)
- [PharmaSUG](#) (5/2021)
- [DIA Annual](#) (7/2021)
- Coming soon-Fall 2021 TransCelerate webinar



Things Not to Do



**MAKE THIS AN
EXCEPTION**



**FOCUS ON
FINANCIAL
ASPECTS**



**GO ALL OR
NOTHING**



**Only focus on
technical aspects**



Thank You!

Stay up to date on MSA Solution Page:

<https://www.transceleratebiopharmainc.com/initiatives/modernization-statistical-analytics/>

Got Questions?

Please direct all inquiries to

info@transceleratebiopharmainc.com

Value Stories

Have a story on how you've implemented our solutions? Let us know by visiting:

<https://www.transceleratebiopharmainc.com/engage-with-us/>

Engage With Us

Have an Idea? Let Us Know!

Give Feedback to an Initiative

Share Your Implementation Experience

We are interested in understanding how the implementation of a TransCelerate solution has added value to your company. Please include your name and email if it's OK for us to follow-up with clarifying questions.

SUBMIT

