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Accomplished leader with 10 years of proven experience in the Life Science industry, specializing in orchestrating and implementing cloud-native data science applications for clinical trials across global biotechnology and pharmaceutical companies.

Holds a Ph.D. in Life Sciences from Jawaharlal Nehru University, India. Expert in cross-functional collaboration in driving product innovation, translating insights from implementations, proof-of-concept initiatives, and pilot programs into scalable product innovations and enterprise business use cases that streamline operations, enhance efficiency and accelerate the clinical development lifecycle for new therapies.





Digital Twins for Clinical Submissions: Simulating Regulatory Review Before Submission

DIVYA KAPOOR, PHD



The Clinical Data
Science Conference

US 2026

22-26 March
Renaissance Austin Hotel



Question 1: How many of you have heard the term 'Digital Twins'?

Question 2: How many of you are aware of the difference between 'Digital Twin' and 'Simulation'?

Agenda

- **Common Pitfalls in Regulatory Submissions**
- **Digital Twin (DT) vs Simulation**
- **Create a Reliable & Effective DT**
- **Regulatory DT**
 - **Architecture**
 - **Process Workflow**
 - **Challenges**
- **GxP-Compliant SCE: Key Enabler for DT Implementation**
- **Future Directions**
- **Conclusion**
- **Q/A**



Common Pitfalls in Regulatory Submissions

Digital Twins: Minimizing Risk and Accelerating Approval in Regulatory Submissions



Data Inconsistencies

- Datasets values not matching with CSR results
- Dataset-define.xml mismatch
- Missing reviewer's guide



Lower-Quality Documentation

- Documents in wrong modules/sections
- Broken or missing hyperlinks
- Appendix referenced but not submitted



Non-Compliance with Regulatory Standards

- Lack of required regional regulatory forms (FDA, EMA, PMDA)
- Errors in formatting or labeling

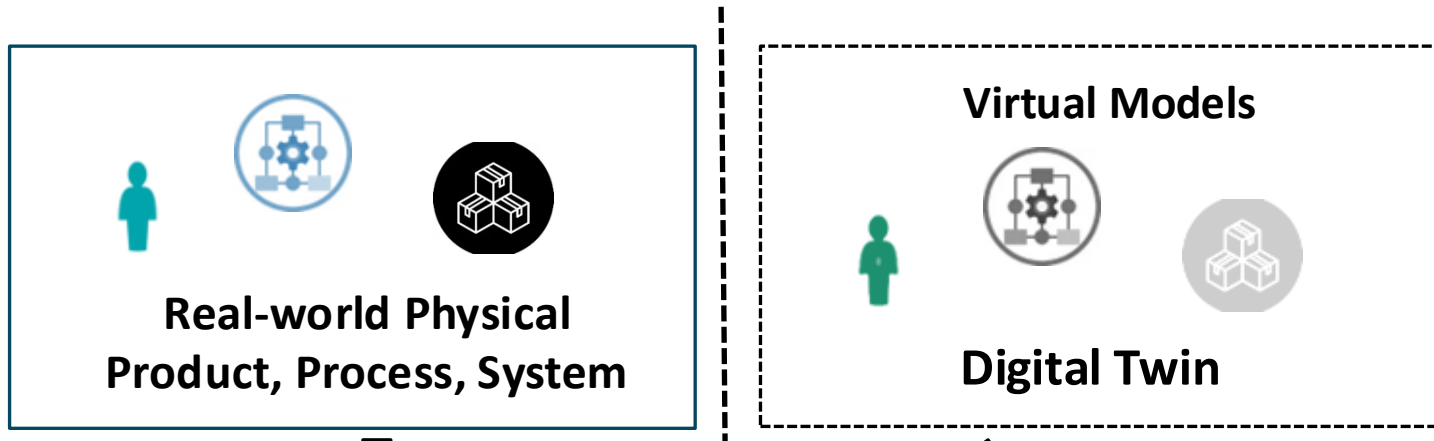


Digital Twin Overview & Key Differences from Simulation

FDA Digital Health and Artificial Intelligence
Glossary – Educational Resource

Digital Twin

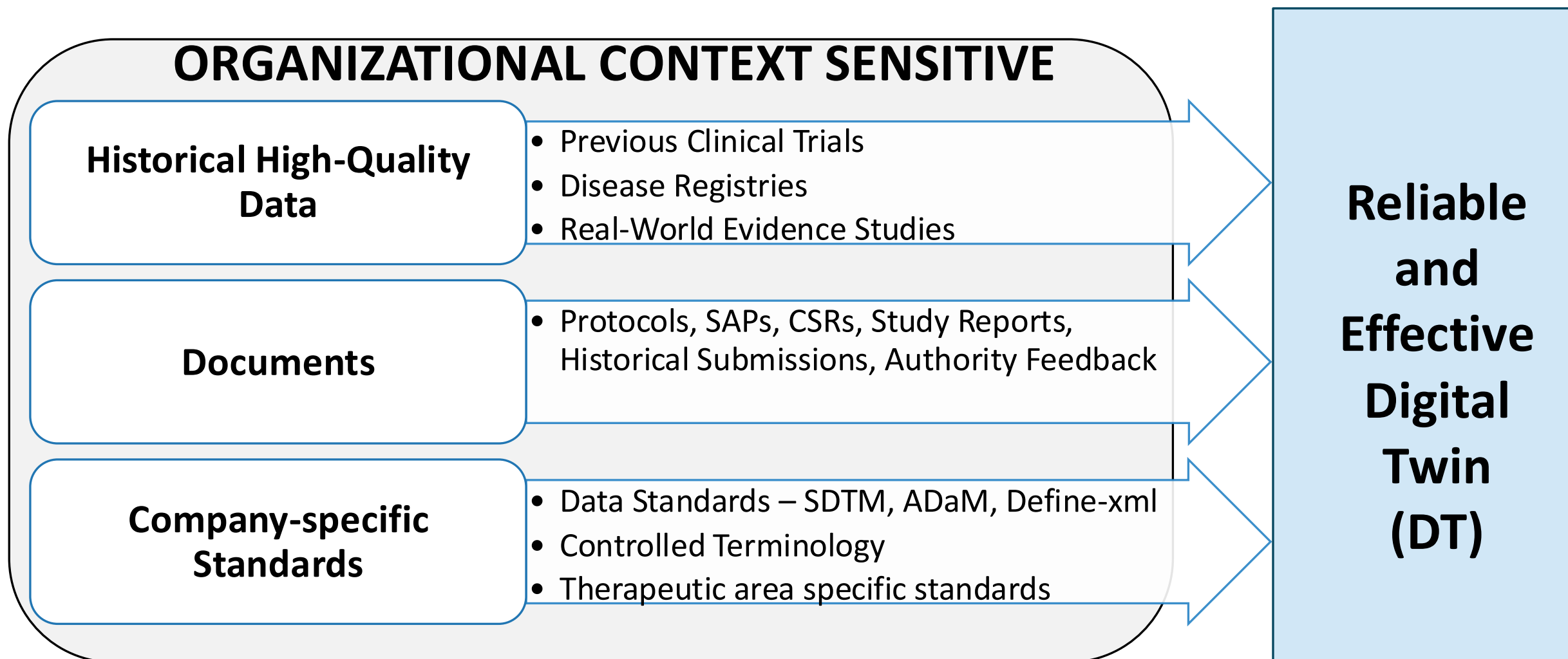
A set of information constructs that mimics the structure, context, and behavior of a physical asset, is dynamically updated with data from its physical twin throughout its lifecycle and informs decisions. The bidirectional interaction between the virtual and the physical is central to the digital twin.



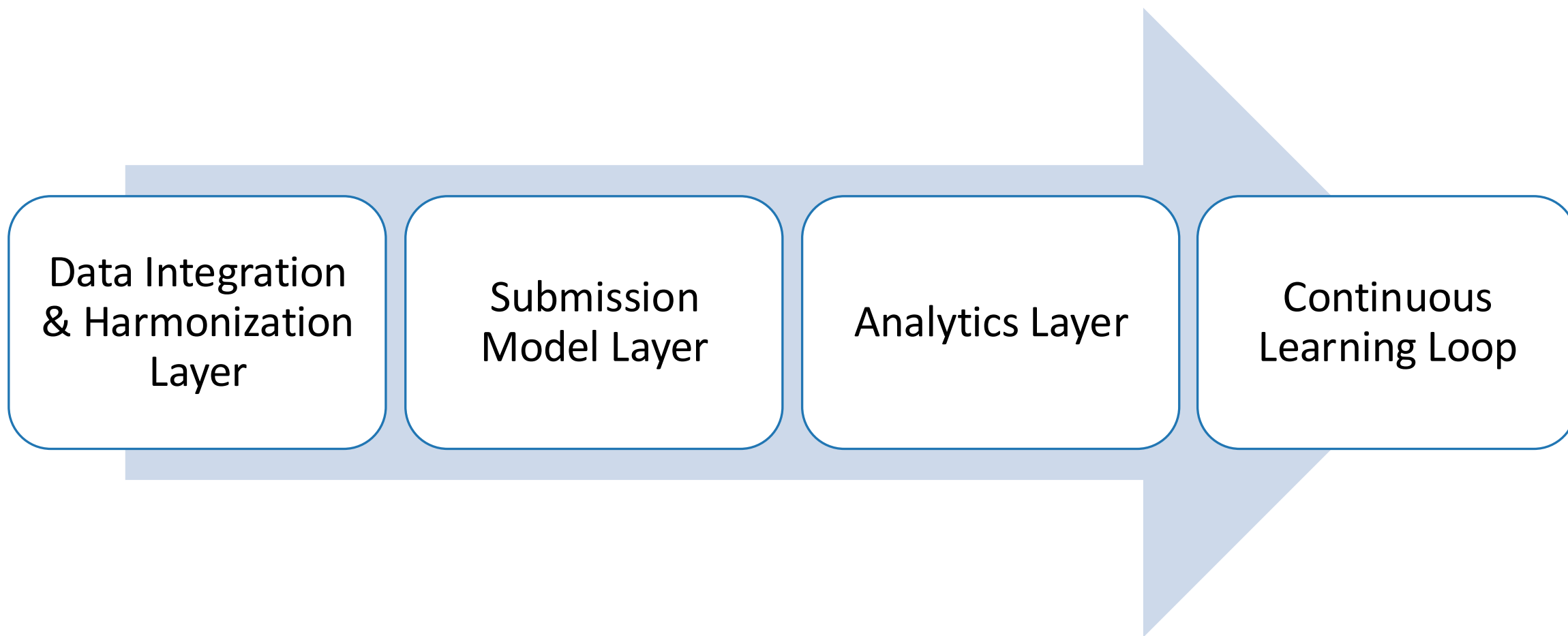
Continuous refinement with real-time data

Digital Twin: Dynamic, Real-time
VS
Simulation: Static, Offline

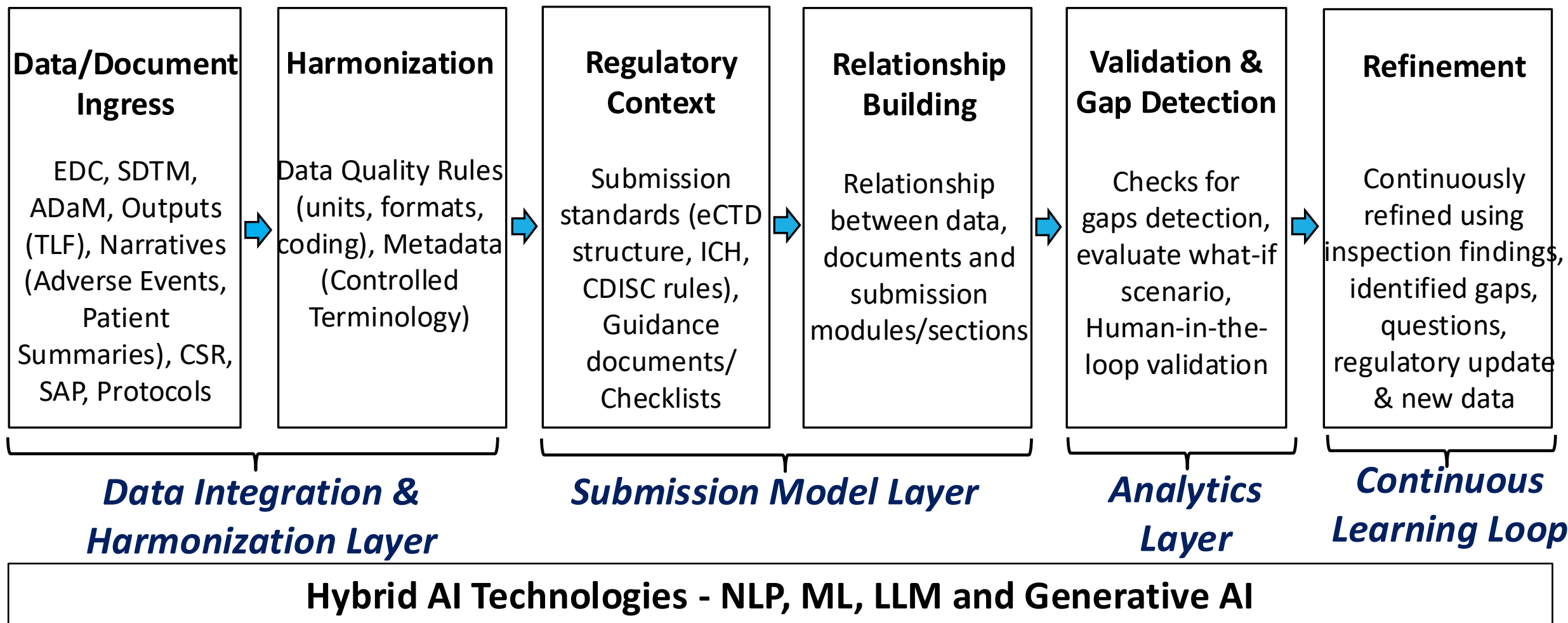
Three Components to Create a Reliable & Effective DT



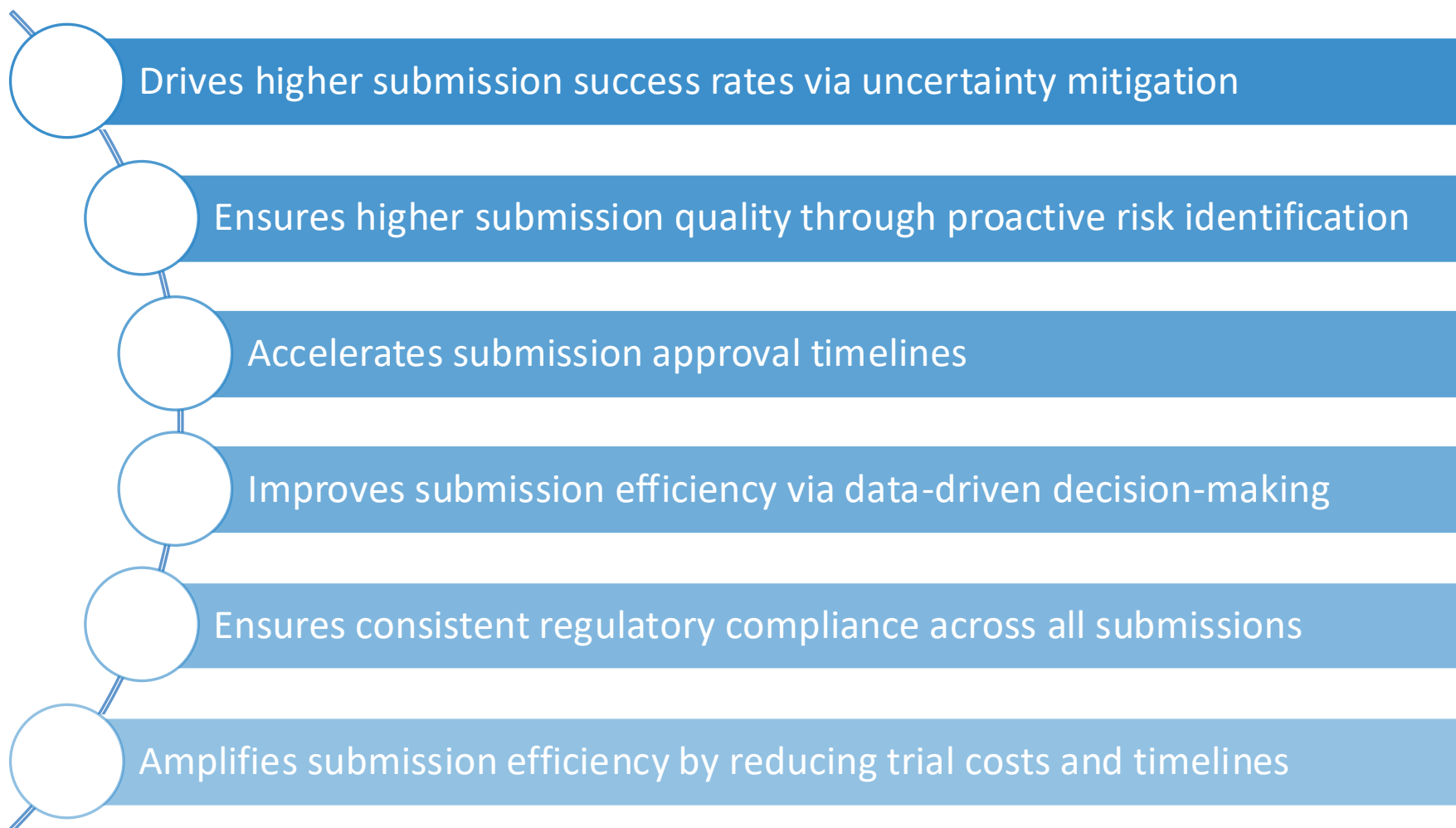
Regulatory Digital Twin Architecture



Regulatory Digital Twin Process Workflow



Regulatory DT Value Proposition for Submissions



Regulatory Digital Twin Challenges

IMPLEMENTATION CHALLENGES

High (Technical/Infrastructural Barriers)

- Data Integrity & Security
- Scalability
- Reproducibility
- Traceability and Audit Trails

Medium (Organization Specific)

- Change Management & Adoption
- Workforce Skill Deficit

REGULATORY CHALLENGES

Medium (Ecosystem Related)

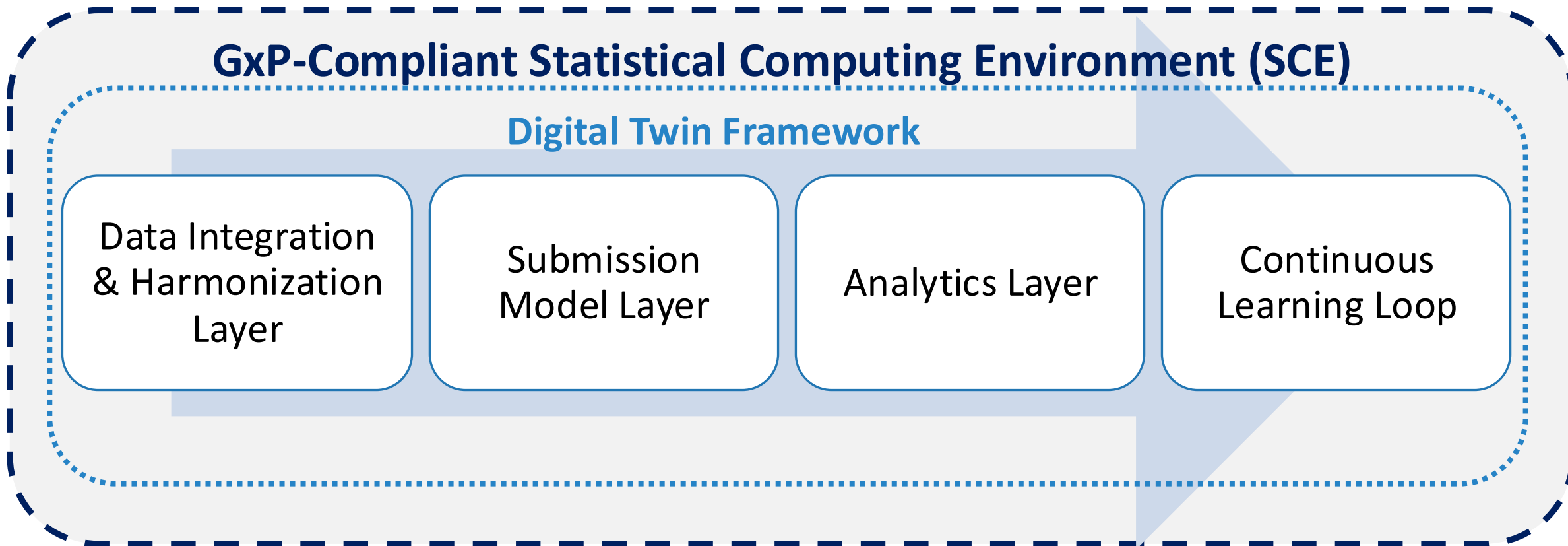
- Lack of interoperable standards
- Evolving Guidelines

Low (Expectations Related)

- Ethical concerns
- Accountability



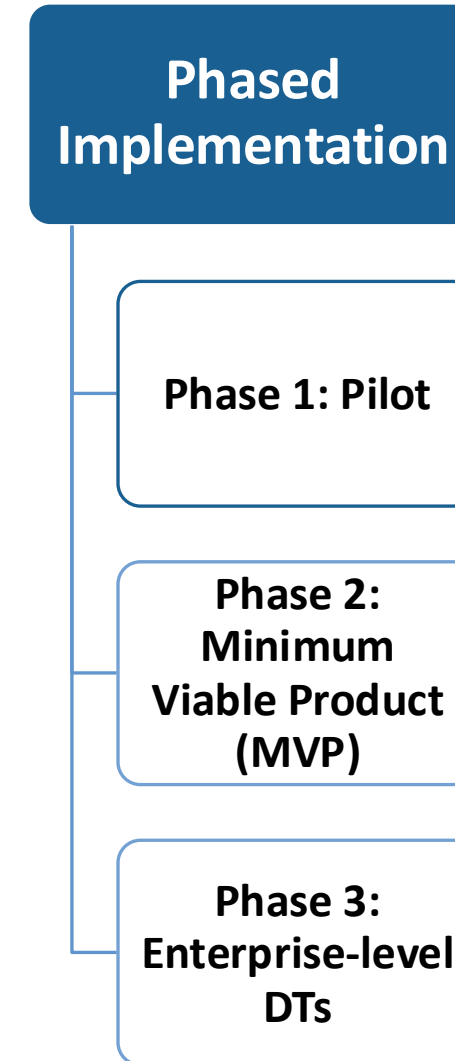
GxP-Compliant SCE: Key Enabler for DT Implementation



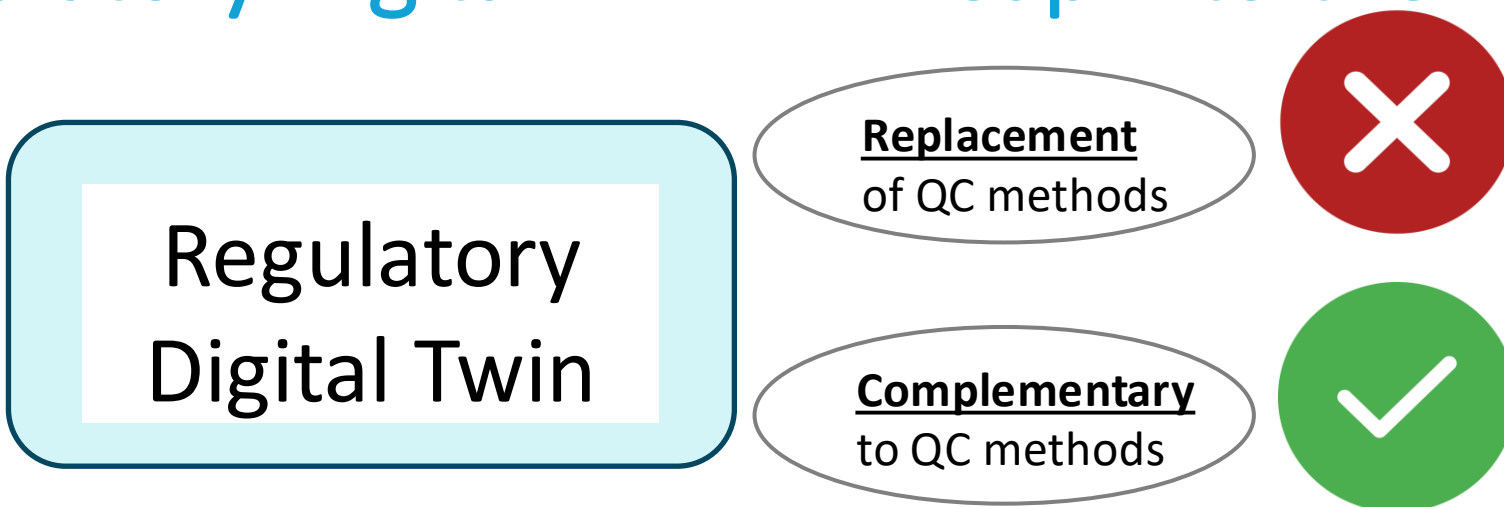
Data Integrity and Security, Role-based Access Control, Versioning, Traceability, Chain of Custody, Reproducibility, Scalable Cloud Computing, Audit Trails

Digital Twin Future: From Static to Dynamic Submissions

- ❖ Pilot studies across **multiple therapeutic areas** to validate DT effectiveness in regulatory submissions.
- ❖ Advancing **regulatory-industry partnerships** to develop guidelines and global interoperable standards for digital twin-enabled submissions.
- ❖ Embracing a **cultural shift** from static, traditional QC to dynamic, transformative DT approach for submissions.



Regulatory Digital Twin: A Leap into the Future



Early Digital Twin integration with downstream QC strengthens **submission quality**, **reduces regulatory queries**, **accelerates first-cycle approvals** and **lowers trial costs & timelines**.

A modern, GxP-compliant SCE provides **data integrity**, **security**, **role-based access**, **version control**, **traceability**, **reproducibility**, **scalability**, and **audit trails**, thereby enabling the successful implementation of enterprise-level digital twins.



Thank You

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