OSMA Spring Meeting

Digitalization in Regulatory/Quality/Clinical Documentation

Veeva

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What is Digital Transformation?

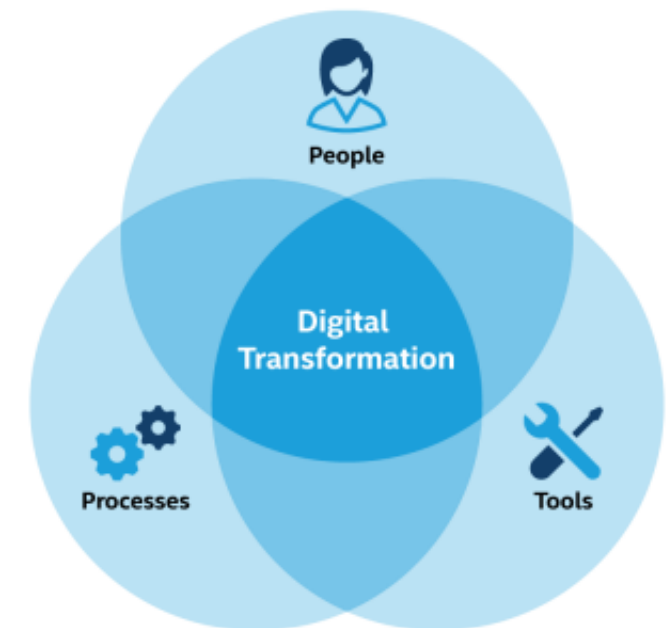Simplifying the way businesses operate

Adopting Technology

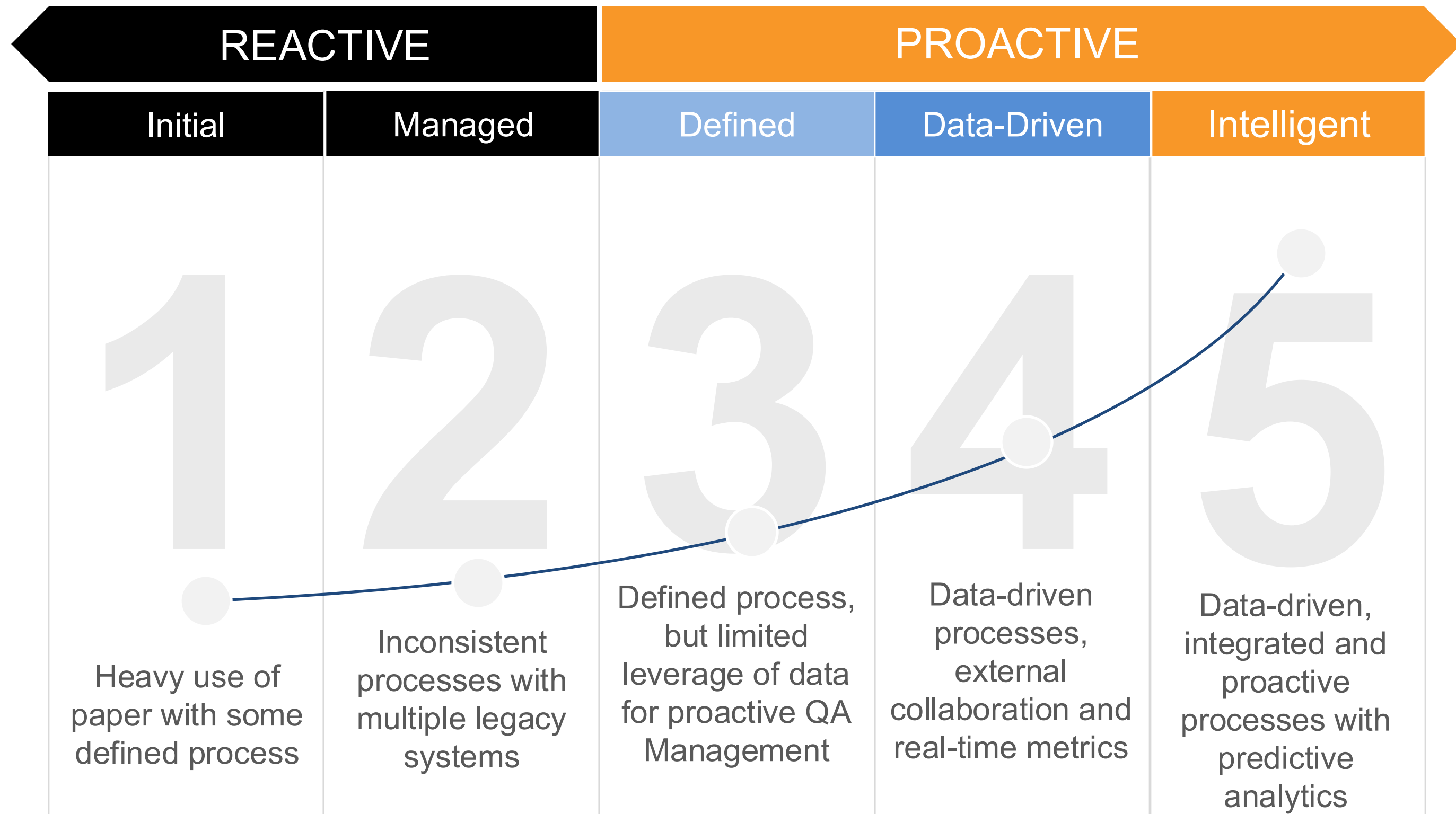Enabling more effective, efficient and transparent processes

Elevating focus on the **PATIENT**

Shifting Organizational **CULTURE**

The Documentation Lifecycle Transformation Curve

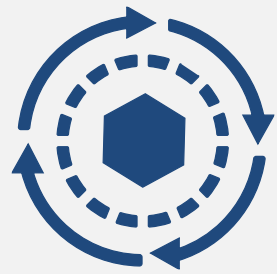| REACTIVE		PROACTIVE		
Initial	Managed	Defined	Data-Driven	Intelligent
Heavy use of paper with some defined process	Inconsistent processes with multiple legacy systems	Defined process, but limited leverage of data for proactive QA Management	Data-driven processes, external collaboration and real-time metrics	Data-driven, integrated and proactive processes with predictive analytics

Proactive Quality Management Requires a Unified Approach

Unified Quality Management connects processes across systems, people, and partners while creating a single source of truth.

➢ Maximize operational efficiency

➢ Enable continuous improvement

➢ Make compliance easy

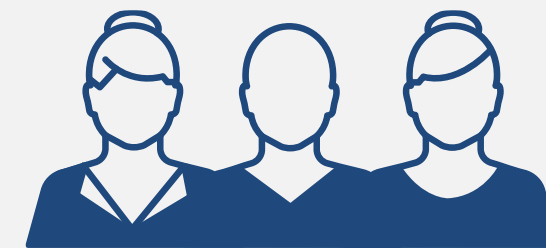# Key Requirements for ensuring success with digitalization

Unified Platform

Harmonize business processes, create single source of truth

Delivered Best Practices

Leverage industry best practice processes to drive standardization, rapidly realize new innovations
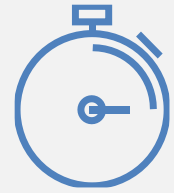
Optimized User Experience

Perform tasks and review data across applications

External Collaboration

Collaborate securely with external partners across disciplines and geographies
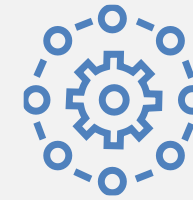
Benefits of digitalization

Reduced Cycle Time and $

- Test and release product faster
- Accelerate change control processes
- Close complaints sooner
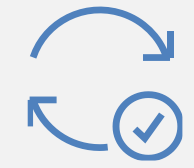- Cost savings and reduction in errors

Improved Usability

- Reduce training with a single, intuitive user interface
- Streamline reporting & analytics
- Standardize workflows
- Enable mobile access
- Streamline compliance and audit readiness

Maximized Efficiency

- Lower cost of compliance
- Standardize processes
- Consolidate and streamline application administration
- Deliver data integrity
- Enhance accuracy and traceability with real-time data
- Centralize data management and collaboration

Connected to External Partners

- Seamlessly extend to suppliers, contract manufacturers
- Enable active collaboration

MDIC's example of digital transformation

Mission towards Digital Transformation

- MedTech manufacturer

- Initiated in 2018

- Initiative to update processes and systems in targeted areas of operations to improve performance and effectiveness

Medical Device Innovation Consortium | Regulatory Science Advancement (mdic.org)