



**How AI-enabled
Structured Content
Authoring is
transforming
documentation across
Regulatory and Drug
Development use cases**

March 24, 2026



Today's Speaker



Todd Georgieff

Industry Lead for Pharma

About RWS

84

of the globe's top
100 brands

8,000

active clients

9 of the top 10
medical device
companies

19 of the top 20
pharma
companies

Sector expertise

Automotive
Aerospace
Defence
Financial Services
Government
Legal
Manufacturing
Life Sciences
Retail
Technology
Telecommunications
Travel & Hospitality

Outline / Story Board

Current State of regulatory submissions and reg documentation

The future vision of AI-enabled regulatory documentation, submission and evaluation

How do you get from here to there?

What are the essential components?

- Structured Content
- Automation-ready content Templates
- AI with traceability for compliance
- Robust workflows with automation
- Integration with upstream data sources/ data repositories
- Metadata-driven instantiation, localization and translation



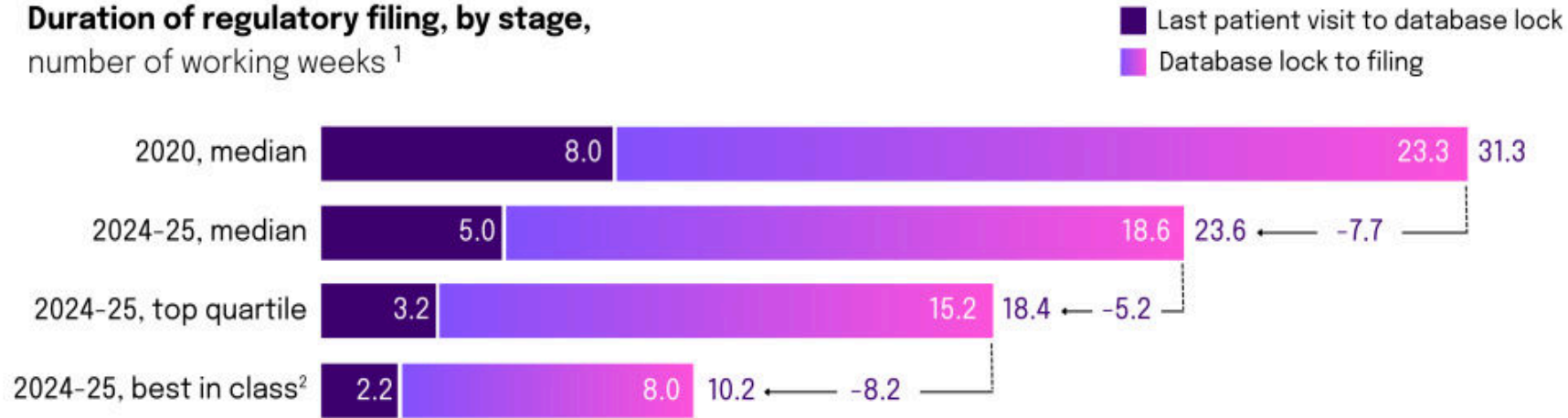
The Opportunity for AI-enabled Structured Content Authoring

Transforming Regulatory Documentation and Submissions
for Pharma, Biotech and CROs

The Motivation for a Digital Transformation

Today's leading pharma companies are filing regulatory submissions up to three time faster than the industry average in 2020.

Duration of regulatory filing, by stage, number of working weeks ¹



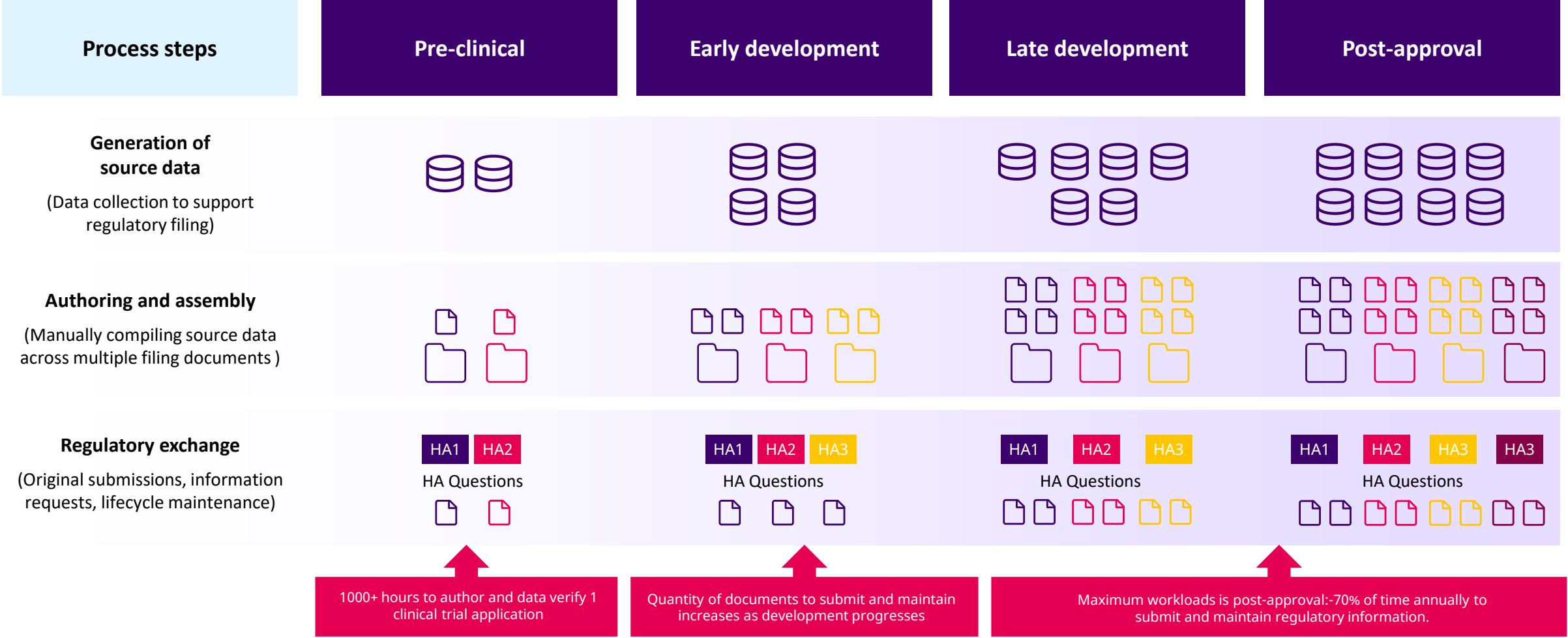
¹From benchmarking of 62 pharma companies. 2025 data as of Q1.

²Speed of top 2 or 3 fastest submissions in benchmarked data set.

McKinsey & Company

¹ This estimate assumes the acceleration from the median timeline in 2020 to the top quartile's timeline in 2024 (an acceleration of roughly 12 weeks), with an NPV of roughly \$60 million per month.

Current State of Regulatory Operations

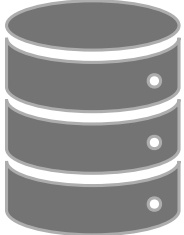


Current Submission Process

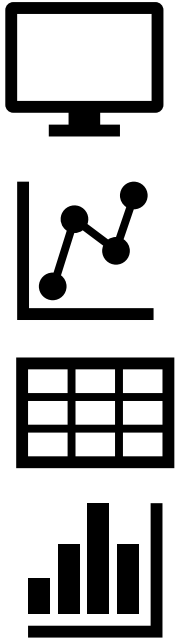
- Module 3: Quality
 - 3.1 Table of Contents
 - 3.2 Body of Data
 - 3.2.S Drug Substance (Name, Manufacturer)
 - 3.2.S.1 General Information
 - 3.2.S.2 Manufacture
 - 3.2.S.3 Characterization
 - 3.2.S.4 Control of Drug Substance
 - 3.2.S.5 Reference Standards or Materials
 - 3.2.S.7 Container Closure System
 - 3.2.P Drug Product (Name, Dosage Form)
 - 3.2.P.1 Description and Composition
 - 3.2.P.2 Pharmaceutical Development
 - 3.2.P.3 Manufacture
 - 3.2.P.4 Control of Excipients
 - 3.2.P.5 Control of Drug Product
 - 3.2.P.6 Reference Standards or Materials



Electronic Gateway



Health Authority Server



Documents versus content components

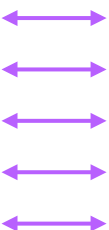


Documents

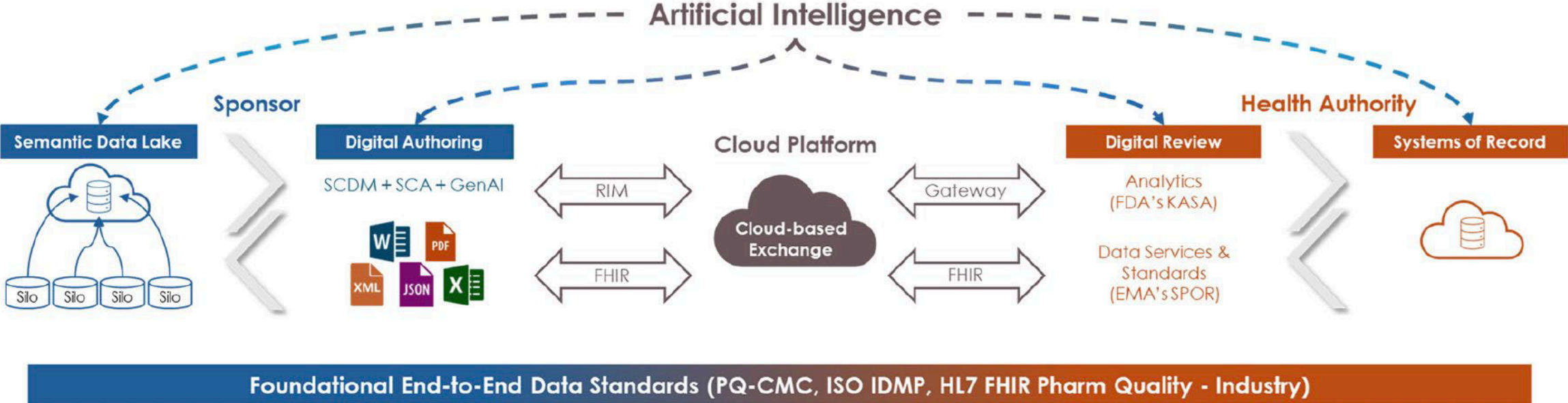
- Monolithic
- Content tied to formatting
- Lack of descriptive data
- Copy / paste quality issues
- Fixed output format

Content components

- Granular, modular, reusable
- Content separate from formatting
- Rich metadata, driving intelligent (re)use
- Fully managed and tracked for compliance
- Any output format, incl. 'traditional' documents



Future State of Regulatory Operations – Use of AI



Benefits of Digitalization

- 
Time Efficiency & Optimization
- 
Manual Error Reduction
- 
Increased Manufacturing Capacity
- 
Reduced Medicinal Waste
- 
Real-time Collaboration
- 
Accelerated Approvals
- 
Global Patient Access

How do we get from here to there?

Structured/Standardized Data and Content Facilitates Automation

STATIC

Table 1. Formulation Buffer Batch Formula

Formula Ingredient	Reference to Standard	Target Concentration	Target Amount per XX kg Batch Size <-Smallest batch>	Target Amount per XXX kg Batch Size <-Largest batch>
<p>* USP = United States Pharmacopeia; NF = United States National Formulary</p> <p>2. X% Polysorbate 20/80 Solution</p> <p>Polysorbate 20/80 is added during drug product formulation as a X% stock solution. The formulation ingredients and amounts for the X% polysorbate 20/80 solution are shown in the table below. The batch size for the polysorbate 20/80 solution is fixed at 1.0 kg.</p>				

Unstructured Content

- Difficult to keep updated
- Time consuming to format
- Limited scalability & reusability

AUTOMATION-READY

Table 1. Formulation Buffer Batch Formula

Formula Ingredient	Reference to Standard	Target Concentration	Target Amount per Batch size [Buffer_minimum] Batch size [Buffer_range] Units Batch Size	Target Amount per Batch size [Buffer_maximum] Batch size [Buffer_range] Units Batch Size
Excipient1 name	Excipient1 grade abbreviation	Strength (Excipient1) Strength.unit	Excipient1 quantity per batch [Buffer_minimum] Quantity.unit	Excipient1 quantity per batch [Buffer_maximum] Quantity.unit
<p>2. Strength [Stock Solution Excipient] Stock Solution Strength [unit] Stock Solution Excipient.name Solution</p> <p>Stock Solution Excipient.name is added during drug product formulation as a Strength [Stock Solution Excipient] Stock Solution Strength [unit] stock solution. The formulation ingredients and amounts for the Strength [Stock Solution Excipient] Stock Solution Strength [unit] Stock Solution Excipient.name solution are shown in the table below. The batch size for the Stock Solution Excipient.name solution is fixed at batch size [Stock Solution] Stock Solution batch size [Stock Solution]units</p>				

Structured Content

- Independent from submission
- Human & machine readable
- Individual building block

ASSEMBLED

Illustrative

Table 1. Formulation Buffer Batch Formula

Formula Ingredient	Reference to Standard	Target Concentration	Amount per 50 kg Batch	Excipient batch quantity per <Enter Batch size [Buffer].maximum >
Proline (USP, PhEur, JP)		220 mM	1280 g	
Ascorbic acid, glacial (USP, PhEur, JP)		20 mM	58.8 g	
Sodium hydroxide, 10M solution (NF, PhEur, JP) a		qs	qs to target pH b	
Water for injection (USP, PhEur, JP)		qs	qs to target weight	
<p>JP = Japanese Pharmacopeia; NF = United States National Formulary; PhEur = European Pharmacopeia; qs = quantum sufficit; USP = United States Pharmacopeia</p> <p>2. 0.01 mg/mL Polysorbate 80 Solution</p> <p>Polysorbate 80 is added during drug product formulation as a 0.01 mg/mL stock solution. The formulation ingredients and amounts for the 0.01 mg/mL Polysorbate 80 solution are shown in the table below. The batch size for the Polysorbate 80 solution is fixed at 1.5 kg.</p>				

Structured Content Authoring

- Automated authoring
- Reuse across documents
- Reduce DV requirements

How do we get from here to there?

STATIC

Table 1. Formulation Buffer Batch Formula

Formula Ingredient	Reference to Standard	Target Concentration	Target Amount per XX kg Batch Size -<Smallest batch>-	Target Amount per XXX kg Batch Size -<Largest batch>-

* USP = United States Pharmacopoeia; NF = United States National Formulary

2. **X% Polysorbate 20/80 Solution**
 Polysorbate 20/80 is added during drug product formulation as a X% stock solution. The formulation ingredients and amounts for the X% polysorbate 20/80 solution are shown in the table below. The batch size for the polysorbate 20/80 solution is fixed at 1.0 kg.

AUTOMATION-READY

Table 1. Formulation Buffer Batch Formula

Formula Ingredient	Reference to Standard	Target Concentration	Target Amount per Batch size [Buffer_minimum] Batch size [Buffer_range] Units Batch Size	Target Amount per Batch size [Buffer_maximum] Batch size [Buffer_range] Units Batch Size
Excipient1 name	Excipient1 grade abbreviation	Strength [Excipient1] Strength unit	Excipient1 quantity per batch [Buffer_minimum] Quantity unit	Excipient1 quantity per batch [Buffer_maximum] Quantity unit

2. **Strength [Stock Solution Excipient] Stock Solution Strength [unit] Stock Solution Excipient.name Solution**
 Stock Solution Excipient.name is added during drug product formulation as a Strength [Stock Solution Excipient] Stock Solution Strength [unit] stock solution. The formulation ingredients and amounts for the Strength [Stock Solution Excipient] Stock Solution Strength [unit] Stock Solution Excipient.name solution are shown in the table below. The batch size for the Stock Solution Excipient.name solution is fixed at batch size [Stock Solution] Stock Solution batch size [Stock Solution] units.

DRAFT

How do we get from here to there?



Document Creation
Content Reuse or Derivation
Content Updates or Versions

Create Summaries

Document Review and Approval

Publishing in RIM

Artificial Intelligence

- Generates first draft of new content
- Optimizes content for context

Generates and refines summary

Enables workflow, QC and metrics

Structured Content Platform

- Manages structured content components
- Ensures use of Templates
- Optimizes training of your LLM
- Tracks and logs reuse for GxP

Stores summaries as controlled content

Controls and tracks workflow

Enables collaborative review

API-enabled RIM upload

Pre-requisites for Generative AI in a GxP Validated Context: Content Management and Structured Authoring

Structured governance is non-negotiable in regulated environments;
unstructured AI deployment cannot ensure compliance or safety

**Training Data
Quality Drives AI
Reliability**

**Grounding AI in
Validated
Content**

**GxP Compliance
Built-In**

**Regulatory
Mandates
Converge on
Structure**

Business Impact

Structured Content and GenAI

FDA Guiding Principles of Good AI Practice in Drug Development - January 2026

Ten Guiding Principles, including:

4. Clear context of use

AI technologies have a well-defined context of use (role and scope for why it is being used).

6. Data governance and documentation

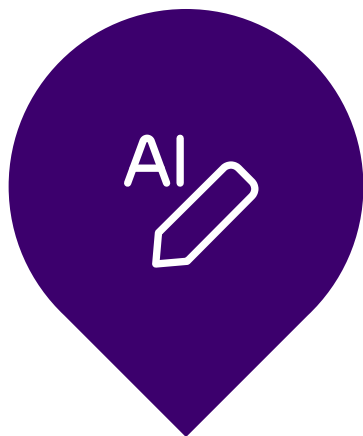
Data source provenance, processing steps, and analytical decisions are documented in a detailed, traceable, and verifiable manner, in line with GxP requirements. Appropriate governance, including privacy and protection for sensitive data, is maintained throughout the technology's life cycle.

Empirical research consistently demonstrates that training data *quality* dramatically outperforms data *quantity* for large language model (LLM) performance.

Curated datasets achieving equivalent or superior results using 1,000-10,000x fewer examples

**SCM and GenAI
Work
Hand-in-Hand**

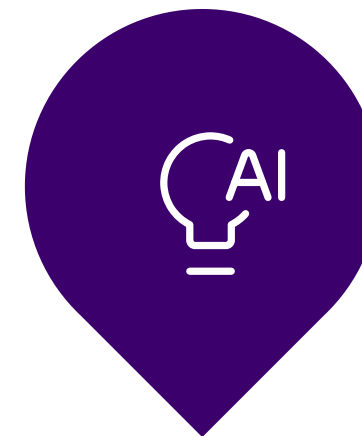
GenAI and structured content – the perfect match



**Generate first drafts,
summaries and conclusions
faster**



**Support FAIR* principles
implementation**



**Use the LLM of your choice
that best suits your needs**

* Findable, Accessible, Interoperable, Reusable

Our proposal

An end-to-end structured content authoring platform

- Content building blocks instead of monolithic documents
- Generative AI (GenAI) supported authoring
- Templates and content reuse replace copy/paste
- High levels of data-driven automation
- Output tailored for each use case and regulatory body

Introducing



rws

Tridion One

Tridion One Product Vision

To help pharmaceutical companies develop and deliver therapies to patients faster by enabling organizations to create, manage, and translate high-quality, compliant content **simply, intelligently, and efficiently** by combining the benefits of AI with the reusability provided by Structured Content Authoring (SCA) and the proven reliability of Structured Content Management (SCM).

The pillars of Tridion One content management



Simple

Enable authors and reviewers to collaborate in real-time using the simple, intuitive, and proven Tridion Editor and Tridion Review online authoring tools.

Tridion One automatically applies formatting, so you can focus on content.

Benefit from the consistency, predictability, and scalability of SCA without having to understand XML.



Intelligent

Utilize both GenAI and Agentic AI to efficiently create and update content using any AI model.

Dynamically generate tables, graphs, and variables from your data lake or other repositories.

Preview a formatted document on demand and export it to multiple formats such as Word, PDF, FHIR, and XML.

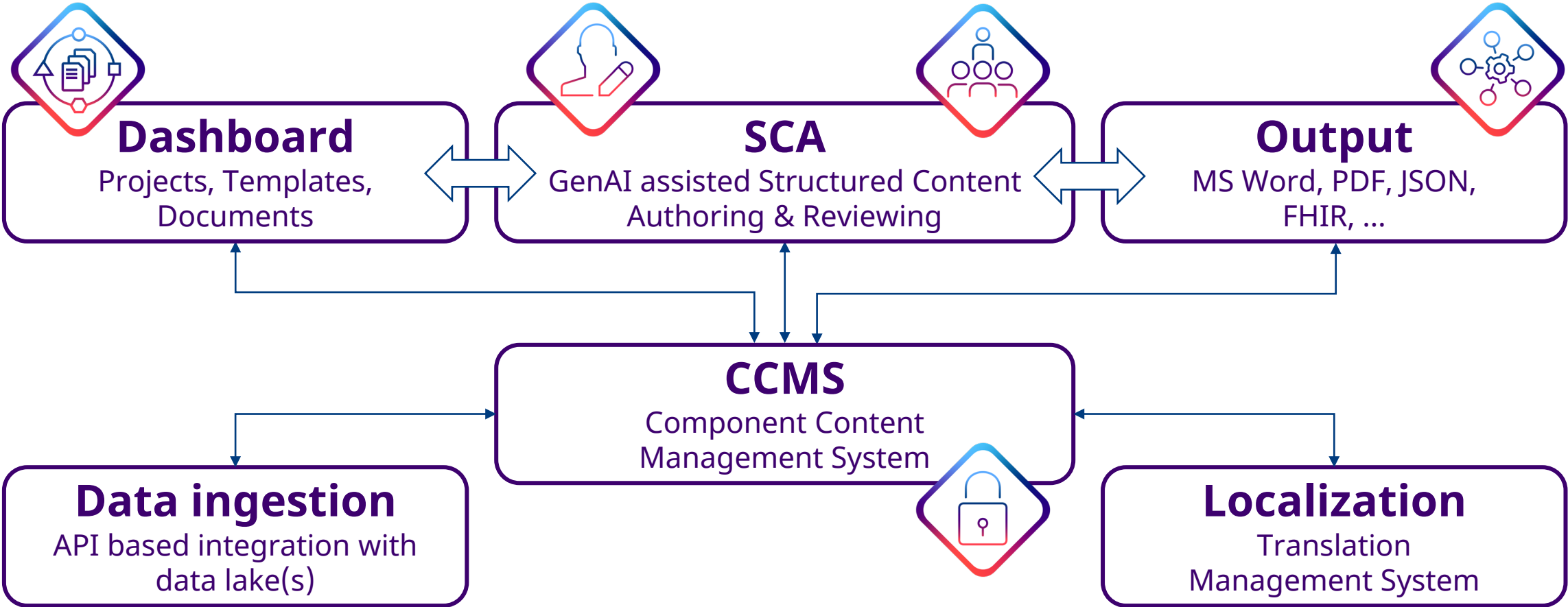


Efficient

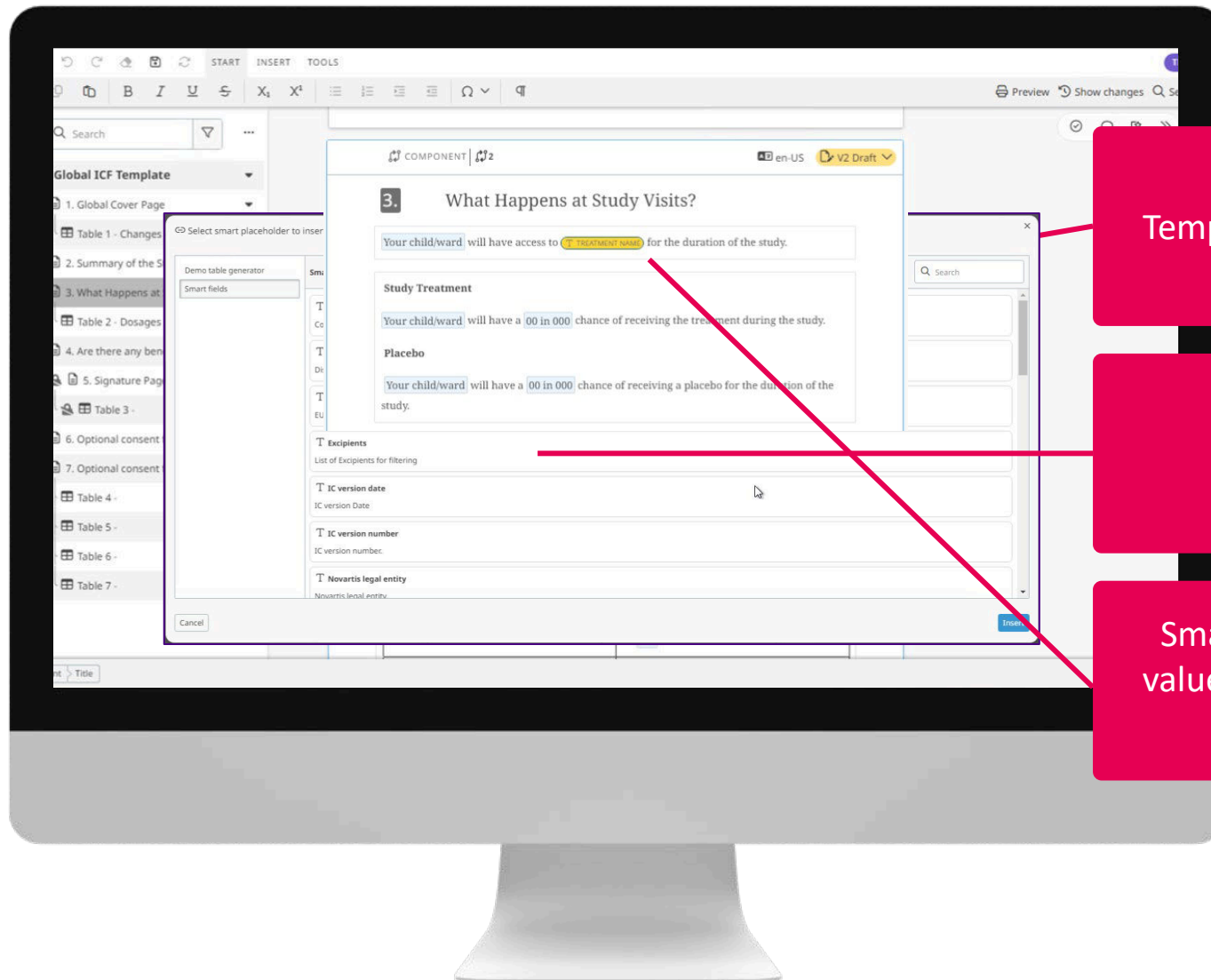
Reuse and manage existing, pre-approved content components to reduce authoring time, prevent unintended variations, and streamline translation.

Tridion One identifies when content or data has been updated, so authors can decide whether to include the changes in other documents.

Tridion One – Solution Overview



Tridion One | Templates and smart placeholders

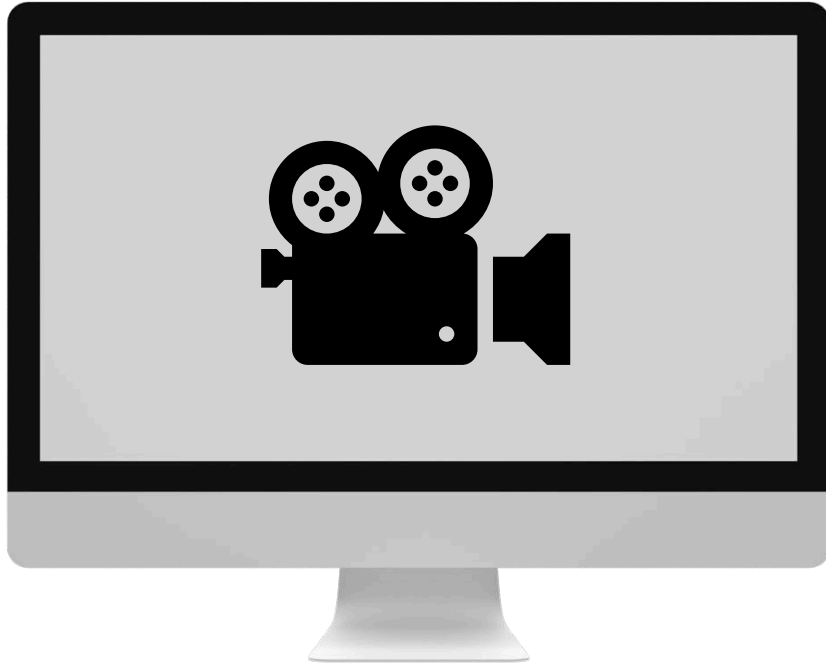


Templates are built from reusable components

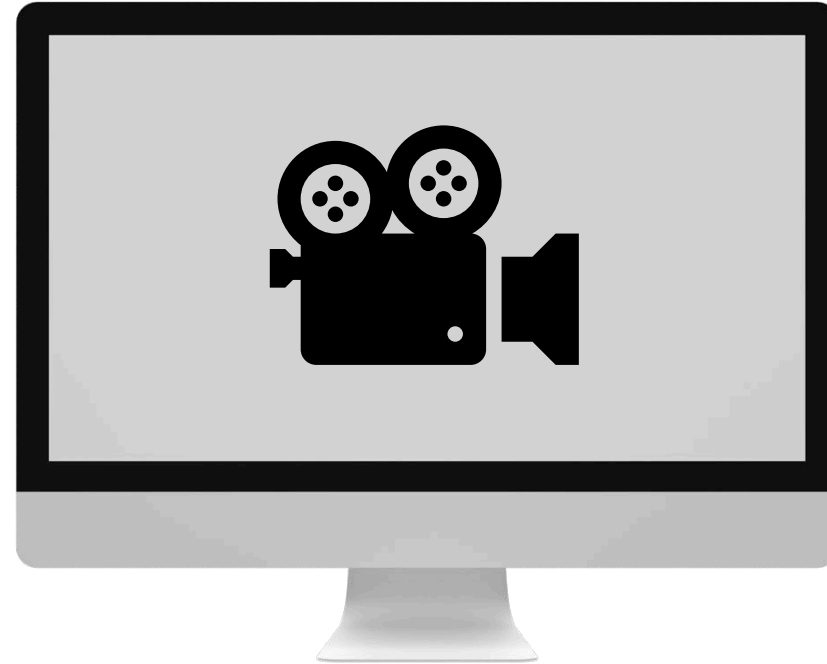
Smart placeholders enable data-driven authoring

Smart placeholders are substituted with real values when a document is instantiated from a template

Let's see what it look s like "in real life"



Demo Video 1
(to be inserted)



Demo Video 2
(to be inserted)

Accelerate time to market with Structured Content



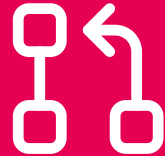
Advanced templating, SCA and GenAI



Integrated translation, content reuse and collaborative workflows



Secure, scalable and future proof



Link content with external data



Robust lifecycle management and audit trails

Tridion One | Business-critical Use Cases



CMC (CTD Module 3)

Advanced Templating

Integration with systems
and Data Sources

API Connection to Veeva
RIM Vault



Regulatory Labelling

Templates (PI, SmPC)

Outputs in JSON, FHIR, DITA

Advanced Localization

Integrated Translation
capabilities



Clinical Development

Protocol, ICF, Clinical Study
Reports

Downstream reuse

Localization and metadata-
driven output generation



Other

Quality Docs (SOPs, other)

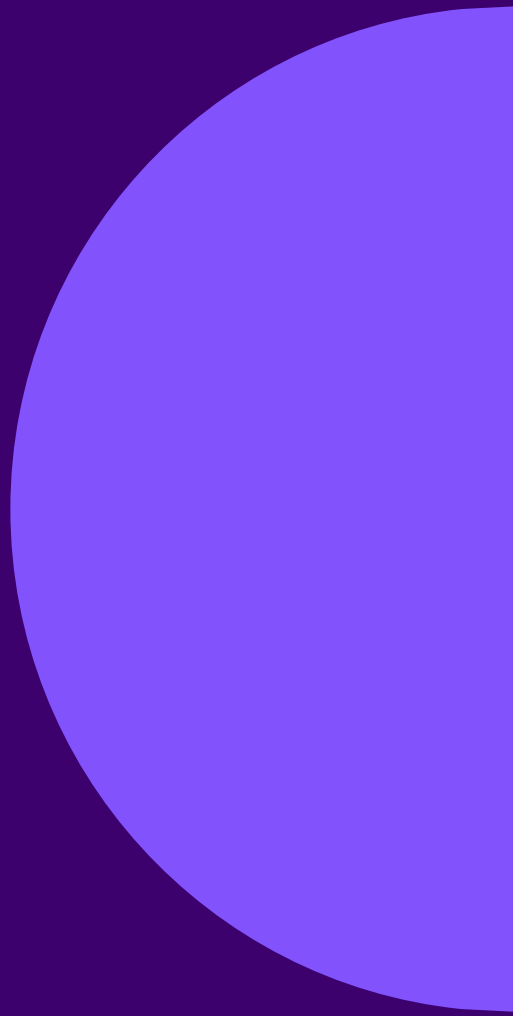
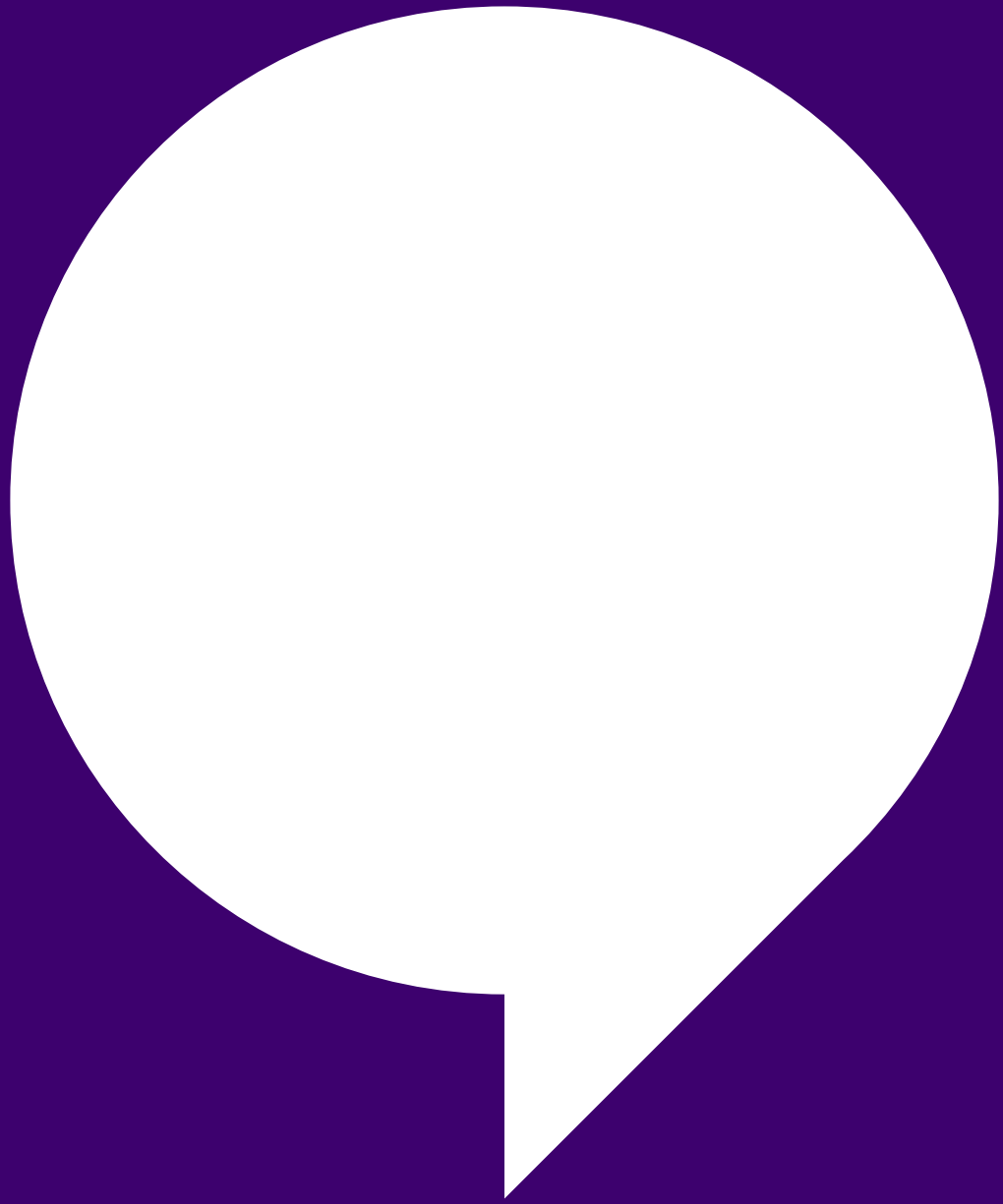
Linkages to Regulatory
justification

Safety Documents (DSURs,
PSURs, RMPs)

Come See us at Booth I13



Talk to us about how you can scale innovation, not paperwork.
AI-ready structured content for faster approvals and better outcomes.





About us

RWS is a content solutions company, powered by technology and human expertise. We grow the value of ideas, data and content by making sure organizations are understood. Everywhere.

Our proprietary technology, 45+ AI patents and human experts help organizations bring ideas to market faster, build deeper relationships across borders and cultures, and enter new markets with confidence – growing their business and connecting them to a world of opportunities.

It's why over 80 of the world's top 100 brands trust RWS to drive innovation, inform decisions and shape brand experiences.

With 60+ global locations, across five continents, our teams work with businesses across almost all industries. Innovating since 1958, RWS is headquartered in the UK and publicly listed on AIM, the London Stock Exchange regulated market (RWS.L).

More information: [rws.com](https://www.rws.com)

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