InteliNotion

Case Study

Structured Authoring – Clinical Documentation

Business Challenges

Our client, a leading global pharmaceutical company, was initiating a pilot phase of a clinical development process improvement program. One of the key objectives of the program was to provide advanced solutions to exploit integrated, standardized clinical information and reuse through implementation of a structured content management and authoring capability. The solution was to achieve improved efficiencies in the regulatory document production processes and to support streamlined change impact assessment through content reuse, with full traceability of the information throughout the product development life cycle.

The pilot was implemented for one of the business areas within Clinical to develop protocol and protocol amendment documents. The successful pilot led to an implementation plan to roll out the solution across the Clinical area and to expand it to other domains across the global enterprise.

The InteliNotion Solution

The InteliNotion platform was deployed for the pilot. The client users configured the platform for their information models and templates for use in the pilot. The client was independently able to conduct the pilot within the platform with some minimal training and enablement from the InteliNotion team. Documents were authored and finalized by business users to evaluate the platform capabilities, potential improvement opportunities and confirm expected outcomes. The client was also able to configure Clinical Study Report (CSR) body templates and verify the document generation, reuse and authoring processes.

The client is in process of executing the implementation phase, as follows:

- Deployment to the client's Azure tenant, using a Continuous Deployment (CD) approach
- Security and access policy configurations
- Operational implementation

The client plans to deploy to the Clinical and Labeling teams initially, with additional plans for incremental enterprise rollout to other functional areas within the next two years.

Value Delivered

With the InteliNotion solution, the client was able to achieve the following benefits:

1. Improved Quality and Consistency
   - Create content once and reuse – improved consistency
   - Control how content is reused (verbatim or editable)
   - Use standardized content
2. Improved Efficiencies
   - Auto-populate relevant content when the document is generated from libraries, metadata values, multiple upstream document reuse
   - Control editability of content
   - Minimize copy/ paste, rewriting, and editing of approved content
   - Avoid re-review and re-QC of preapproved content
3. Generate Multiple Outputs from Single Source
   - Documents – original format, redacted, and specific for audience
   - XML – can be used for other opportunities (e.g. disclosures, publish to ClinicalTrials.gov, FDA pilot review system)
4. Improved Change Management
   - Understand and manage impacts of content change effectively, with visibility to everywhere content is reused
   - Complete visibility to the variants of the content artifacts that have been created, and where they are used