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Managing Clinical Content to improve quality, optimize authoring and review process, and enhance study design.

Virtify® SCM

Virtify SCM applies asset management principles to clinical content to achieve collaborative and efficient document creation, improved quality, enhanced productivity, and increased compliance.

Virtify SCM Clinical provides:

- **Tight Integration with Microsoft Word**, allowing users to author content in the document - centric way they're used to.
- **Improved Quality** of clinical documents by ensuring content is accurate, up-to-date, and consistent.
- **Improved Compliance** with changing organizational and regulatory requirements.
- **Enhanced Productivity** through automated document generation, concurrent authoring and review, and reduction in review cycles.
- **Process Optimization** by centralizing the project management of clinical deliverables and simplifying task management and resource allocation.
- **Improved Study Design** by leveraging intelligence from clinical documents.

The Problem: Managing the Complexities of Creating, Maintaining, and Leveraging Clinical Content

Clinical documents are sophisticated and essential communications which serve as the foundation for bringing innovative products and therapies to market. Information contained in these documents must support continued investigation, development, and marketing for decades.

Due to high barriers to entry, including long development cycles, high costs, and increasing regulatory and ethics requirements, clinical content is a critical enterprise asset. Achieving efficiency when generating high-quality clinical content is key to reducing cost and continuously improving clinical content and study design.

Yet, the traditional approach to clinical document authoring locks high-value content inside the document, making it extremely difficult to locate, use, and leverage. The inefficiencies which result from the document-based authoring and storage paradigm have a significant impact on the cost of clinical and regulatory activities, the agility of the enterprise to respond to changing market and regulatory needs, the quality of clinical information, and the capacity for new product development.

The Solution: Structured Content Management

Virtify SCM provides state of the art content management capabilities while offering the familiarity and ease of use of Microsoft® Word for writing, reviewing, and editing tasks. Thus, with Virtify SCM, users continue to author and review content in a document-centric way, while the organization benefits from the application of asset management principles to clinical content.

Virtify SCM intelligently inventories clinical content assets as they are created using Microsoft Word, eliminating the need to create a complete content library before the benefits of structured content management can be realized.

Virtify SCM automatically tracks where content is used and how it changes over time. Understanding the lineage and evolution of content enables Virtify SCM users to improve the quality and compliance of clinical documents while shortening document authoring and review cycles.

Virtify SCM, Intelligence from the clinical development process can be used to improve future study design, allowing the enterprise to achieve a competitive advantage by improving returns on clinical content assets and reducing risk.



KEY BENEFITS

Ease of Adoption:

Virtify SCM provides a document-centric authoring experience through its tight integration with Microsoft Word, virtually eliminating retraining and reducing process change.

Improved Content Quality:

Virtify SCM automatically notifies content authors and reviewers when content is updated. By ensuring that document authors are working with the most recent and accurate content, consistency in documents across the same program is achieved. Higher quality content results in fewer and shorter review cycles.

Increased Productivity:

Virtify SCM's intelligent content reuse capabilities automatically reuses relevant content in related documents, significantly shortening authoring time and increasing accuracy. Coauthoring and concurrent review features allow multiple users to generate or review content at once, further reducing cycle time for authoring, review, and approval tasks.

Reduce Risk:

By managing master content and tracking content lineage in Virtify SCM, the users are equipped to identify, assess, and mitigate clinical and regulatory risks. Authors and reviewers are helped in understanding why decisions were made.

Improved Organizational Compliance:

The ability to manage clinical content centrally makes quality and regulatory compliance much more manageable. Using workflow coupled with visibility into content lineage, the organization is able to enforce standards for the authoring, edit, review, approval, and tracking of clinical content.

Improved Operational Decision-Making:

Virtify SCM improves operational decision-making by ensuring trial managers, clinical investigators, ethics committees, and other key decision makers have the most accurate and up-to-date information available.

Increased Business Agility:

Virtify SCM records the origin, modifications, and usage of all content over time, enabling an organization to better understand complex regulatory communications, more rapidly respond to regulatory queries, and determine impacts as new information becomes available.

Process Optimization:

Virtify SCM's workflow and project management features provide management with a centralized view of resourcing, task status, and the progress of clinical authoring projects. This eliminates the need to manage projects in an external system or via email, facilitating collaboration and streamlining project timelines.

Enhanced Operational Intelligence:

Virtify SCM Reports and Analytics features provide visibility into system utilization and performance, as well as the return on clinical content assets.

Enhanced Study Design:

By harvesting intelligence from the clinical development process and prior projects, Virtify SCM allows users to leverage prior experience to continuously improve study design and the quality of clinical documentation.

Increased Efficiencies in Downstream Processes:

The management of master content and intelligent reuse features of Virtify SCM allows the organization to expedite the initiation of downstream processes and creation of downstream documents. For instance, the generation of the Informed Consent Forms and Case Report Forms can be automated based on approved Clinical Protocol content.

Integration with Existing Systems:

Virtify SCM can be readily integrated with existing infrastructure including document management systems, taxonomy management systems, protocol design tools and identity management systems.

Simplify Trial Disclosure and Redaction Tasks:

Virtify SCM reduces the effort required to meet and manage increasing clinical trial disclosure requirements. Through the use of Virtify SCM's rendering engine, medical writing teams can quickly and effortlessly produce redacted documents during the writing process, increasing efficiency by eliminating post-publishing redaction and QC.

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For more information on Virtify's software, services, or other products please contact:
Phone: +1 (617) 301-8700 E-mail: sales@virtify.com Website: www.virtify.com