Why does the clinical document development process need to change?

There are a myriad of clinical documents that are developed and published during the journey that a therapy goes through from concept to approval. Critical clinical documents must be developed to the highest possible quality. For any clinical trial team the development of the protocol, CSR, SAP, investigator brochure, consent forms, regulatory and safety documents, or contracts it is an exhaustive process involving countless collaborators. But the approach to developing these clinical documents has not changed significantly over the years; most companies still run a process that looks very much like a paper-based process supported by word processing.

Cognizant® Document Accelerator

Transforming the clinical document development process for the digital era.

Cognizant Document Accelerator – a new paradigm for clinical document development, authoring and review.

Cognizant Document Accelerator was uniquely designed to simplify drafting and producing clinical documents, saving time, ensuring quality through adherence to internal corporate standards and best practices, and creating a digital foundation for automating later steps in the clinical development and approval process. Document Accelerator provides real-time collaboration with complete oversight and project management from start to document completion.
Life sciences companies are coming to recognize the value that could be unlocked by simplifying and streamlining the clinical document development process. These documents are crafted by highly skilled individuals, whose time is not best spent wrestling with complex templates, applying formatting and searching for useful reusable content.

In many cases, companies choose to run a cautious process to ensure through review and maximize document quality. But it is also clear that the current methods are not producing high-quality outcomes. Research from the Tufts Center for the Study of Drug Development (1) notes that “Despite a rigorous and intensive internal review and approval process, the majority of finalized protocols are amended multiple times”, with nearly half of all amendments deemed to be avoidable.

It's time to transform the clinical document development and collaboration process.

Cognizant Document Accelerator is a new and unique digital documentation system designed to allow collaboration in drafting clinical research documents. Conceived with a different mindset and driven by extensive research and collaboration with clinical and scientific writers, clinical document development becomes a truly collaborative experience where text becomes data that can be exploited and reused throughout the clinical research, submission, contract and approval process.

By adopting our SaaS-based platform, in days your teams will be able to:

• Manage templates and library content for simple reuse, so you can embed standards and best practices
• Create documents in a fit-for-purpose collaborative environment
• Improve processes with effective task management and tracking
• Exploit content as a digital asset, helping to drive automation in the clinical development process

Collaborative, standards-based clinical document creation has arrived.

Document Accelerator is uniquely designed to address the rigor needed for drafting clinical documents while incorporating an enterprise perspective towards authoring and review, collaboration, process management security and standards enforcement, and downstream content reuse.

Putting the author experience first while still delivering on the benefits of structured content management and component-based authoring sets Document Accelerator apart from prevalent word processing tools and content management platforms in use today. Seamless task management and process oversight ensures submitted documents are ready for final review and approval, improving first-time approval rates and minimizing costly amendments. More importantly, individuals can concentrate on content — not formatting — and benefit from saving time while helping improve quality through improved collaboration, review and adherence to company standards and best practices.

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Key Features and Benefits

Collaborative authoring and review for higher quality output and shorter completion timelines.

Subject-matter experts can be assigned as Authors and Reviewers on specific sections of a document, where they can work simultaneously with other authors. Section-based document development and review allows for faster development and completion. The product’s built-in and configurable workflow capabilities track status and notify users of next steps. Revisions and comments are made on a single copy of the evolving document, eliminating the need for managing multiple versions as authors gather, collate and sift through additions, edits and comments from multiple reviewers and documents. Example text features prompt authors to reuse relevant content if desired. It’s easy to set up users and roles with complete configuration of access control to the system and to individual documents, down to the section level.

Template and standards management ensure accelerated document set-up and more consistent output.

Document Accelerator features simple template creation and management, optimizing the user experience when working on a new document. The many pages of instructions and example text included in a typical Word template have been moved outside the body of the document, but are still accessible when needed within each section of the document template, making the template itself cleaner and easy to use.

Any existing document template can be configured in the system. The product also includes the TransCelerate Common Protocol Template (CPT), Statistical Analysis Plan (SAP) and Clinical Study Report (CSR) and associated library content out-of-the-box optimized within our user interface for improved usability.

Collaborative authoring and review for higher quality output and shorter completion timelines.
**Dynamic Template Set-Up**

Through the use of configurable set-up screens for each document template type, a simple set of information selected from drop-down lists or provided by the user when setting up a new document for use allows the system to automatically select the correct template and associated template configuration information. Documents can be set up to inherit content from other documents and text can be configured to preload into a new document based on metadata or keywords. This dynamic set-up allows for the correct help and sample text to be loaded and variations of templates to be correctly configured eliminating guesswork and the need to search for the correct template type. Controlling the use of the correct template and preloading a significant amount of relevant content can help reduce the risk of errors and allows authors to use the most up-to-date and approved templates and boilerplate content.

**Automatic Formatting**

One of the most frustrating aspects of collaborative document development is the formatting of the final document. Most companies have specific formatting styles for clinical, regulatory, safety, contract and other documents. In an environment where individual contributors and reviewers have their own copies of documents the initial pre-set formatting of a document can become diluted, mutated or lost.

Document Accelerator removes the burden of formatting for document authors. Each section of a document is a simple text window. Some basic formatting is allowed within each section and will carry through to the final Word document export. Once a document is ready for review, approved corporate formatting is applied when the document is exported to Word. This helps teams comply with required formatting and allows authors to focus solely on content, removes a time consuming tedious manual step and saves a significant amount of time to get the final document to those who need it most.

Template and standards management ensure accelerated document set-up and more consistent output.
Content Library drives quality and consistency through building and maintaining a repository of standardized content for reuse.

Many sections of a clinical document consist of significant levels of standard, boilerplate or reference content that is applicable to many other clinical trial, regulatory, submissions, approval or contract documents. To that end, one of the most powerful features of Document Accelerator is its searchable content library. The library gives authors access to a rich set of approved, relevant content for inclusion in documents. Through a “Librarian” role, standard content can be quickly created, version controlled and tagged with keywords to make searching for relevant content painless. Smart content reuse capabilities can not only help save time, authors can be confident that the content pulled from the library are consistent with previously approved language. This can reduce the entire team’s time needed for document review and approval.

Transforming the document into a digital asset adds value to the entire clinical development process.

Clinical documents contain essential information that is needed for other documents, systems or processes involved in the spectrum of clinical research. Today, that information needs to be manually extracted from the document and often interpreted or manipulated to make it fit for purpose in an individual downstream process, tool or application. Every manual intervention introduces the possibility of inconsistencies or errors that could seriously impact the overall quality and integrity of those downstream activities, processes or systems.

All content created in Document Accelerator can be readily extracted as structured, machine-readable digital output, creating the opportunity for key portions of the clinical document to be used automatically to:

- Configure eClinical systems such as EDC and RTSM/IRT
- Submit trial information to clinical trial registries
such as ClinicalTrials.gov, EudraCT and WHO ICTRP
- Generate content for other deliverables such as case report forms, operational manuals, statistical analysis plans and clinical study reports
- Compare procedures in the SOA with endpoint and expected outcome information
- Key information exported to clinical analysis, RBM or other systems
- Enable integration with metadata repositories

**Process oversight and metrics help leaders manage and optimize document delivery.**

With all activity taking place in a single platform, Document Accelerator provides unique oversight and detailed metrics on the overall document development status, and on Author and Reviewer activity as the document progresses to completion.

Tasks can be allocated to individuals through simple notifications, and deadlines can be set and tracked. The system logs all activity, including the number of users accessing the system during document development.

Reports summarize review comments categorized by section and type. Simple charts and reports provide a complete overview of the peaks and troughs of activity during the development of the document. This unique visibility of the actual effort that goes into document development can give insight that can be used to identify process optimization opportunities. Tracking issues raised during the commenting process can uncover problems with document instructions and clarity of section requirements among other issues.
Document Accelerator paves the way for digital clinical documents

At every step in the clinical development process, clinical documents are the blueprints that enable a therapy to come to market. Document Accelerator is the logical starting point for a digital content strategy designed around quality assurance and a “write once, use many times” philosophy, and for a true digital data flow throughout the clinical trial process.

It’s time to stop producing simple text-based documents, and instead create digital information that can drive the clinical development and approval process. Document Accelerator transforms the clinical document development process, finally bringing it into the digital era.

All content created in Document Accelerator can be readily extracted as structured, machine-readable digital output.
Learn more

For more information or to request a demo, visit https://www.cognizant.com/accelerator/clinical-trial-protocol-design.

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world’s leading professional services companies, transforming clients’ business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 194 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.

Cognizant Solutions Overview

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