Why does the protocol development process need to change?

The protocol lays out the scientific basis for testing the viability of a new therapy, alongside the vital operational and regulatory controls that ensure the safety of all participants. Such a critical document must be developed to the highest possible quality, so it’s no surprise to any clinical trial team that the development of the protocol is an exhaustive process involving countless collaborators. But the approach to developing a protocol 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.

Life sciences companies recognize the huge value that could be unlocked by simplifying and streamlining the protocol development process. A trial cannot start until the protocol is approved, so every day spent working on the document adds a day to the time it will ultimately take to bring a new treatment to patients need it. Protocols are crafted by highly skilled scientists, whose time is not best spent wrestling with complex templates, applying formatting and searching for useful reusable content.

The protocol document provides the foundation for every step in a clinical trial.

Cognizant Protocol Creator was uniquely designed to simplify everything about producing a protocol document, saving time, ensuring quality through adherence to standards and best practices, and creating a digital foundation for automating later steps in the clinical trial process.

In many cases, companies choose to run a cautious process so they can ensure quality is not sacrificed in favor of speed. But it is also clear that the current methods are not producing high-quality outcomes. Well-documented research from the Tufts Center for the Study of Drug Development notes that “Despite a rigorous and extensive internal review and approval process, the majority of finalized protocols are amended multiple times.” In fact, 57% of protocols have at least one substantial unforeseen amendment, with nearly half of all the amendments deemed to be “avoidable.” Each amendment leads to an estimated three months of unplanned delay and over $500,000 in unbudgeted costs.
It’s time to transform the protocol process.

Cognizant Protocol Creator is a new and unique digital documentation system designed for clinical trial documents. Conceived with a different mindset and driven by extensive research and collaboration with scientific writers, protocol development becomes a truly collaborative experience where text becomes data that can be exploited and reused throughout the clinical trial process.

By adopting our cloud-based platform, which requires no installation and minimal set-up time, 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 the required documents in a fit-for-purpose collaborative environment
• Improve processes with effective task management and tracking
• Exploit content as a digital asset, driving automation in the whole clinical trial

Collaborative, standards-based protocol creation has arrived.

Because Protocol Creator was built by authors, for authors, it’s uniquely able to accommodate how scientists work, but with 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 Protocol Creator apart from prevalent word processing tools and content management platforms in use today. Seamless task management and process oversight ensures submitted documents are complete and thoroughly reviewed, improving first-time approval rates and minimizing costly amendments. More importantly, scientists can concentrate on content — not formatting — and benefit from saving time while ensuring quality through improved collaboration, review and effortless adherence to standards and best practices.

Key features and benefits

Collaborative authoring and review for the highest quality output in the shortest possible time.

Protocol Creator was designed specifically for scientific authors. Subject-matter experts can be assigned as Authors and Reviewers on specific sections of a protocol document, where they can work simultaneously with other authors. Section-based protocol 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 protocol, eliminating the need for managing multiple versions as authors gather, collate and sift through additions, edits and comments from multiple reviewers and documents. Suggested text features prompt authors to reuse relevant content if desired.

It’s easy to set up users and roles (such as Authors and Reviewers) with complete configuration of access control to the system and to individual protocols, down to the section level.

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

Protocol Creator allow 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 protocol template, making the template itself cleaner and easier to use.

Any existing protocol template can be configured in the system. The product also includes the TransCelerate Common Protocol Template and associated library content out-of-the-box optimized within our user interface for improved usability.

If required, variations of templates can be set to support different trial types, and a simple set of information entered when setting up a new trial allows the system to automatically select the correct template. Protocols can be set up to inherit content from other documents, text can be configured to preload into a new protocol document based on metadata or keywords (indication, phase, etc.); and protocols can be published to preformatted Word or PDF documents.

Controlling the use of the correct template and preloading a significant amount of relevant content greatly reduces the risk of errors and ensures authors always use the most current standards and best practices. Applying all formatting in a final publishing step saves a significant amount of time at the end of the process.

**Content library** drives quality and consistency through building and maintaining a repository of standardized content for reuse.

Many sections of a protocol document consist of significant levels of standard, boilerplate or reference content that is applicable to nearly every clinical trial.

To that end, one of the most powerful features of Protocol Creator is its searchable content library. The library gives authors access to a rich set of approved, relevant content for inclusion in the protocol document. 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 not only save time compared to repeatedly creating from scratch, but also ensure the same concepts are expressed in consistent, approved language from trial to trial. This reduces the time needed for review and approval.

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

With all activity taking place in a single platform, Protocol Creator provides unique oversight and detailed metrics on the overall protocol 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 protocol 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 protocol development gives new insight that can be used to identify process optimization opportunities.

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

The protocol document contains essential information for nearly every system or process that is used in the rest of the clinical trial. 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
Protocol creator paves the way for digital clinical trials

The protocol is the blueprint for a clinical trial, which makes it 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 protocols as simple text-based documents that describe the clinical trial, and instead create digital information that can drive the clinical trial. Protocol Creator transforms the protocol development process, finally bringing it into the digital era.

the overall quality and integrity of the clinical trial. All content created in Protocol Creator can be readily extracted as structured, machine-readable digital output, creating the opportunity for key portions of the clinical trial 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
- Enable integration with metadata repositories to embed the use of standards