Cognizant®

Reduce Time and Complexity of
Clinical Trial Documentation
with
Cognizant Protocol Creator

Meticulous documentation plays a vital role in ensuring clinical trials comply with important regulations that help to safeguard all participants, and the clinical trial protocol document provides the foundation for every step in the trial. Ensuring that the design, objectives and operational methodology for the trial are detailed in this comprehensive document requires exhaustive effort and great care. Cognizant® Protocol Creator™ is uniquely designed to simplify everything about producing the 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.

TRANSFORM PROTOCOL CREATION THROUGH DIGITAL AUTHORING

Cognizant Protocol Creator is a digital documentation experience designed specifically for the teams of highly skilled scientists that produce clinical trial protocol documents. With quick access to re-usable content and an author-focused user interface, Cognizant Protocol Creator reduces the time and effort involved in creating protocol content. The online review module transforms the complex, cross-functional document review process into a collaborative and transparent experience. Overall process management is simplified through effortless assignment of authors and reviewers and clear oversight of tasks and deadlines.

Cognizant Protocol Creator allows users to recreate any existing template in the software's intuitive interface, where standard text, instructions and examples can be accessed with ease. Simplified text editing allows authors to concentrate on the content itself, while the software automatically manages the structure and formatting for the final document. Users can load the configurable library with best-practice content, enabling simple browsing and selection for use in documents. The TransCelerate Common Protocol template and associated library content comes pre-configured in the software, eliminating reliance on cumbersome customization to support the use of these valuable standards.

More than a document creation system, Cognizant Protocol Creator transforms protocol content into a structured digital asset, which can be managed by section and tagged with metadata. This digital structure enables document authors to control how the final protocol content is consumed – whether as traditional documents or as machine-readable output.

KEY BENEFITS

Streamline Protocol Authoring – Cognizant Protocol Creator provides an intuitive interface designed especially for scientific authors. With section-by-section management tools, authors can greatly streamline the content creation process, by assigning users to specific document sections, as well as giving them easy access to time saving features including embedded instructions and library content.

Implement Standards – With built-in support for the TransCelerate Common Protocol Template, as well as the ability to add any other custom template and custom library content, Cognizant Protocol Creator provides authors the ability to reuse approved content easily. This reuse greatly reduces the risk of errors, and ensures authors are always using the most current standards and best practices.

Enable Downstream Efficiency – Authors can easily publish protocol documents to Word or PDF formats, but Cognizant Protocol Creator also enables authors to export content to structured formats. Exporting this way provides machine-readable output that can be consumed by other applications more efficiently, creating opportunities for automation which could unlock significant additional benefits to the clinical trial process.

Improve Collaboration and Oversight – Cognizant Protocol Creator is a web-based solution, providing a single platform to handle the entire protocol development process. Authors collaborate on a single version of the document, with tasks and workflows organized by document section. Reviewers can add comments and view each other's comments in real-time. Document owners have access to a comprehensive dashboard for oversight of the document, simplifying the tracking of activities, tasks and deadlines.

COGNIZANT PROTOCOL CREATOR FEATURES

Intuitive Interface – Cognizant Protocol Creator is uniquely designed to simplify clinical trials protocol authoring, and our interface is specific to this important process and the highly skilled scientists who lead it.

Document Control – Cognizant Protocol Creator centralizes all content authoring for protocol documents in a web-based repository, so members of a protocol team can work on the same version of the document simultaneously. Authors can collaborate on an individual section or the whole document, and a document owner can easily track and manage the entire document creation process with our task and date management features and advanced activity metrics and reports.

Template Management – Cognizant Protocol Creator allows simple configuration of any existing template. Users can create a library of standard content and approved reusable text that can be easily loaded into new documents, and support for the TransCelerate Common Protocol Template comes pre-configured.

Multiple Format Export – Once content is completed and reviewed, a document owner can publish the protocol document as a formatted Word or PDF document, but Cognizant Protocol Creator stores the document as a structured digital asset. This approach enables the content to be managed as data and exported in more efficient formats, like JSON. Other systems that may require the inputs from the protocol can consume this structured output readily, and perhaps automatically.

Role-based Security – Cognizant Protocol Creator features robust role-based security management, so a document owner can limit access to specific content sections, documents and capabilities.

LEARN MORE

Cognizant Protocol Creator offers a powerful digital authoring experience that greatly reduces the manual effort involved in producing the protocol documents for clinical trials.

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

ABOUT COGNIZANT

Cognizant is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Their unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses.

Headquartered in the U.S., Cognizant, a member of the NASDAQ-100, is ranked 195 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

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