synchrogenix

A CERTARA COMPANY

Artificial Intelligence Technology

ClinGenuity Redaction Management Service

Study Report Writer

Narrative Builder

Artificial Intelligence Technology

The use of Artificial Intelligence (AI) technology is revolutionizing life sciences through contextual understanding, natural language processing, and deep learning. It will continue to enable advancements at unprecedented rates. Through the use of our SaaS-based AI, natural-language processing technology, Synchrogenix has developed an approach that is able to process through context-based understanding rather than being based on a structural reliant methodology. Our solution in the area of regulatory and medical writing truly meets the promise of automated authoring and is also the most effective and efficient approach to mitigate risk for meeting data transparency requirements.

At Synchrogenix, we know it's almost impossible to fully standardize every element of Regulatory documents within sponsor organizations. This is compounded by increased in-licensing and collaboration with other institutions, partners, and academia. Unlike other technologies, Synchrogenix's platform interprets any template or document structure with minimal training. Sponsors access the tool through a web interface and follow these simple steps:

- Choose the document type to be created.
- Drag and drop source files from the desktop.
- Place the document into your personal queue and view real-time progress.
- Retrieve the document once complete, typically within one to three days.

ClinGenuity Redaction Management Service

Our ClinGenuity Redaction Management Service (CRMS) is the only AI-enabled redaction technology solution in the marketplace. Our technology is capable of automatically traversing thousands of pages and millions of words to identify and redact sensitive information with more than 99% accuracy. Synchrogenix has now processed over 6500 reports and has completed 65+ European Medicines Agency (EMA) Policy 0070 submissions.

Most recently, Synchrogenix has been preparing to engage in more advanced anonymization techniques, such as quantitative risk assessment, by combining machine learning with the latest Open Application Programming Interface (API) platform at https://w3dev.openpharma.io.

Study Report Writer

Study Report Writer is an AI-assisted writing tool that automates the generation of regulatory documents. It is able to generate 80% of a first draft within 24 to 48 hours depending on the size of source input files. The source input files are:

1. Trial protocol
2. Statistical Analysis Plan
3. Tables, listings, and figures

Our technology allows the writer to focus on scientifically valuable activities such as data interpretation and key message development by automating tasks such as copy-and-paste, table population, and tense. Our system also evaluates data in tables to create fact-based, noninterpretive results text. We are saving two to three weeks of authoring time, leading to cycle time and cost benefits. The consistency that is a fundamental element of our AI approach also significantly reduces the number of reviews required by half.

Narrative Builder

As a complement to our Study Report Writer or as a stand-alone solution, Synchrogenix's Narrative Builder generates narratives quickly, efficiently, and consistently. Typically, projects that include greater than 50 narratives per study benefit most from the support of AI technology.

As part of the initial auto-narrative generation process, the majority of information is pulled directly from the sources. The AI technology does the heavy lifting. With up to 80% of the narrative auto-generated, only manual editing is needed to ensure that the story is focused. We are able to generate consistent narratives every time, which reduces the review cycles down to just one. Two to four weeks of programming time are eliminated, as our AI technology uses the source SAS SDTM/ADaM datasets instead of programmed patient profiles. Uniquely, our AI technology processes not only the clinical database but also the safety database/CIOMS forms. Furthermore, only a one-time configuration is needed to ensure that the narrative template is followed for each and every study.

Through our Narrative Builder service, we have the ability to manage thousands of narratives to full completion, including review, in less than thirty days. Recently, Synchrogenix generated 730 narratives with full QC and finalization in less than five business days.

For more information, visit our website at **www.synchrogenix.com** or email **contactus@synchrogenix.com.**

Synchrogenix - Regulatory and Communications Strategy, Science, and Solutions

Synchrogenix provides regulatory and communications strategy, science, and solutions to life science companies worldwide. Our regulatory expertise and innovative technology bridges the full regulatory continuum to propel treatments to the market by meeting the needs of all stakeholders and improving public health outcomes.

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