CERTARA

Synchrogenix Transparency Service Case Study: Sponsor B

Background

Sponsor B, a top-10 pharmaceutical company, supports policies and actions that seek to appropriately enhance scientific exchange. They are committed to providing access to anonymized patient data and full Clinical Study Reports (CSRs) from their clinical trials to qualified scientific researchers. They are supportive of the European Federation of Pharmaceutical Industries & Associations (EFPIA) and Pharmaceutical Research and Manufacturers of America (PhRMA) guiding principles on data sharing. They strive to ensure that clinical data is published in a timely manner, objective, accurate, and balanced, regardless of the outcome of the trial.

Challenge

Sponsor B has committed to posting synopses of CSRs from clinical trials of new medicines or new indications for approved medicines submitted after January 1, 2014, to its company website. Sponsor B has also committed to complying with the European Medical Agency (EMA) Policy 70, requiring the public posting of CSRs for all clinical reports submitted for central marketing authorizations after January 1, 2015. Additionally, Sponsor B has had multiple EMA Policy 43 Freedom of Information (FOI) requests come through with very short notice and turnaround times.

As a result of the various posting requirements, Sponsor B required that multiple document types be made available to the public for different purposes with each requiring a separate set of rules. In order for these reports to be made publicly available, all personal data (PD) relating to patients, study administrators, and any other individuals named in the reports and company confidential information (CCI) had to be redacted or blacked out prior to publication.

Differing sets of rules for different document types made it nearly impossible for a fully manual effort to accomplish this task. They struggled to manage this internally or with their traditional strategic partners from both a time and quality perspective.

Synchrogenix's technology-enabled service was an attractive solution to meet Sponsor B's complex redaction needs.

Solution

Powered by ClinGenuity, Synchrogenix's unique artificial intelligence (AI) engine is built on natural language processing and recognition. As such, the engine is able to identify individual words, parts of speech, word combinations, and phrasing combinations automatically and, therefore, can determine context. Because of the power behind Synchrogenix's unique AI, the engine can be configured to automatically identify PD and CCI the same way a human would be trained to identify them. The process of identifying and redacting sensitive information therefore becomes automated and significantly more accurate.

Layered on top of the technology is a team of domain-specific experts. Synchrogenix's redaction team performs a thorough quality control (QC) review of each and every document, ensuring the highest level of accuracy. Findings and resolution of findings are documented on a quality review checklist form and are then seamlessly integrated into the system and used to refine the accuracy of the tool in real time.

The increased accuracy provided by the engine and expert redaction team, which focused solely on redaction day-to-day, enabled Synchrogenix to provide a highly accurate product across 7 different document types for Sponsor B.

As stated, one of the initiatives driving the redaction of several of Sponsor B's document types was the need to comply with the EMA FOI Policy (EMA Policy 43). Through the FOI policy, researchers are able to request from the EMA any documents used by the EMA in their drug approval decision-making process.

Once a request has been deemed appropriate, the EMA redacts the requested document. Sponsor B found some inconsistencies in the way the regulators redacted their data and were able to use Synchrogenix-generated versions to cross-check and correct PD and CCI redactions.

Synchrogenix uniquely generated an unapplied version of the redacted report with redactions highlighted and redaction rationale comments applied. This allowed Sponsor B to communicate with the regulators and justify its corrections.

Summary

After a thorough vetting process, Sponsor B chose Synchrogenix as its transparency partner. Synchrogenix was seamlessly able to handle the full synopses redaction needs for Sponsor B. Sponsor B was able to prepare in advance of and in conjunction with the implementation of Policy 70. And, Sponsor B, as early as the on-boarding phase with Synchrogenix, started relying upon Synchrogenix to provide an unapplied version of the same documents redacted and provided by the EMA under the FOI policy.

Sponsor B used the Synchrogenix-unapplied version to perform a side-by-side comparison against the EMA-redacted draft. Then, Sponsor B was able to complete a redaction table to submit to EMA, listing any redactions that differed between the 2 drafts.

Through this process, Sponsor B was able to react quickly to EMA Policy 43 requests, with Synchrogenix managing each redaction within 48 to 96 hours, depending on the document size, and provide more thorough feedback to the EMA regarding additional suggested redactions for their documents.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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