CERTARA

Synchrogenix Transparency Service Case Study: Sponsor A

Background

Sponsor A, a top-10 pharmaceutical company, committed to publishing Clinical Study Reports (CSRs) for clinical outcome trials for all medicines that reached the market, dating back to the formation of the company since its last merger. Sponsor A set an objective to become the most transparent pharmaceutical company in the industry and provide leadership that would ultimately drive transparency across the whole industry.

Challenge

This resulted in the need to prepare 2000+ reports for disclosure, dating back to December 2000. They prioritized this activity by its top-selling medicines. They issued a press release stating that this would be available on their Clinical Trial Register within an 18-month period.

They also committed to disclosure at the point of "market authorization" or termination of assets once a study had been published for all prospective studies.

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.

Sponsor A invested some time in developing the guidance that would govern the redaction of PD and CCI within their reports. However, the sheer volume of the project required resources beyond what Sponsor A could handle internally.

Solution

At first, Sponsor A turned to offshore outsourcing to implement the large-scale redaction project. In their first 12-month period, Sponsor A had only completed the redaction of five reports. Sponsor A also found it difficult to assess the accuracy of PD redaction, as there was no mechanism to see and explain the rationale for removal. As a result of slow turnaround times and poor quality, Sponsor A's transparency team quickly came to the conclusion that offshore outsourcing was not a viable solution. Sponsor A had zero tolerance for the accidental exposure of PD data that could lead to further litigation.

Sponsor A chose to investigate Synchrogenix's technology-enabled redaction solution and consultancy services to further develop its PD rules. 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 Personal Identifiable Information (PII), 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.

Result

Sponsor A partnered with Synchrogenix to complete full redaction of over 2000 CSRs within a two-year time period. The balance of the reports would be completed in follow-on contracts. Within a three-month time period, Synchrogenix completed the sponsor's on-boarding to include configuring the system to Sponsor A's specific set of rules, training a dedicated review team to understand and review against Sponsor A's specific rules, and redacting several reports in a testing mode prior to going live. Once live, Synchrogenix released 20–30 units (roughly 30 CSRs) per week in order to meet the 2000+ report volume requirements in a two-year time period.

Additional Scope

Three-quarters into the project, Sponsor A determined that their CSRs contained a type of document that was often copyrighted, the clinical outcome assessment (COA). COAs measure a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions. Sponsor A did not hold the COA copyright and, therefore, had to go back and ensure that this data was removed.

Synchrogenix was able to configure its AI system to identify and redact COAs, utilizing a database list of copyrighted COAs. The database was researched and developed by the expert redaction team. Within a period of 1.5 quarters, Synchrogenix retroactively reviewed all of the CSRs that had already been released in the prior three-quarters and prospectively implemented the new COA redaction process in all CSRs going forward.

Summary

Synchrogenix used their extensive experience in medical and regulatory writing practices to support Sponsor A's further refinement of its PD and CCI rules. Synchrogenix has become the market leader for its expert knowledge of transparency guidelines, rules, best practice, and regulatory authority regulations. Sponsor A is a member of the non-profit organization TransCelerate BioPharma, which is made up of the 16 top pharmaceutical companies. TransCelerate has now adopted Synchrogenix consultancy in relation to transparency rules definition and guidelines across its members.

Through the use of an AI solution, combined with an expert and industry-leading QC team, Synchrogenix allowed Sponsor A to move from a run rate of five redacted reports per year to almost 1500 reports per year, at a quality of 99.99% non-PD disclosure accuracy.

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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