synchrogenix

A CERTARA COMPANY

Transparency & Disclosure

65+
EMA Policy 0070 Submissions

99% Accuracy

Advanced Anonymization

Crowdsourcing Engagements

Participant Engagement, Transparency, and Disclosure Services

Synchrogenix provides expertise, services, and technology, not only to meet transparency and disclosure requirements, but also as a complement to our commitment to enhance engagement of study participants and the general public in drug development. Synchrogenix produces anonymized and redacted datasets and clinical documents; authors Informed Consent Forms (ICFs), plain language study design and results summaries, and other plain language documentation; and supports protocol registration and disclosure of study results. Synchrogenix addresses sponsor-specific initiatives and risk tolerance while maintaining compliance according to established policy guidelines and industry watchdog measures.

Clinical Trial Postings and Results Disclosure

The demand for transparency and disclosure of clinical trial data continues to grow. Disclosing clinical trial information and creating transparency of data are key steps toward increasing engagement, trust, and data utility. These, in turn, are expected to spur new products and therapeutic approaches, and enable sponsors to avoid unnecessary trials.

Synchrogenix provides the following services:

- Accurate and efficient assessment of current sponsor compliance with posting on ClinicalTrials.gov, EudraCT, and other applicable worldwide registries; preparation of remediation plans; updates or completion of entries; and creation of future robust processes, including Standard Operating Procedures and Work Instructions.
- Routine clinical trial registration and disclosure of results, including redaction of clinical trial protocols and statistical analysis plans.
- Experienced consulting and project leadership across process components to ensure that transparency requirements are met in the most optimal manner.

Redaction and Anonymization

Redaction

- Company Clinical Transparency Programs
- EMA Policies 43 and 0070
- NIH Final Rule
- FDA Clinical Data Summary
- Upcoming Health Canada Transparency and Openness Regulation

The Synchrogenix ClinGenuity Redaction Management Service (CRMS) is the only artificial intelligence (AI)-enabled redaction technology solution in the marketplace. It can identify and redact sensitive information with more than 99% accuracy. Our AI solution is supported by expert reviewers who ensure that trials with specific challenges, such as small populations or rare diseases, receive the customized approach that they require. In addition, our experts assist sponsors with the authoring of anonymization reports. Synchrogenix has now processed over 6500 reports and has completed 65+ European Medicines Agency (EMA) Policy 0070 submissions. Our redaction process supports EMA, Food and Drug Administration (FDA), and upcoming Health Canada requirements.

Anonymization

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. Our methodology is based on Synchrogenix's internal expertise in the implementation of probability of re-identification and K-Anonymity, adhering to the PhUSE Clinical Data Interchange Standards Consortium (CDISC) Data de-identification standard for Study Data Tabulation Model (SDTM).

All Synchrogenix Anonymization APIs are designed using the Open API Specification—implemented as Swaggerized RESTful APIs, with standard, language agnostic, machine-readable interface descriptions, callable from a browser interface through a published Uniform Resource Identifier (URI) or programmatically consumed by other APIs.

Crowdsourcing Engagement

Synchrogenix authors high-quality ICFs and plain language study design and study results summaries.

- ICFs and plain language study design and study results summaries support Pharmaceutical Research and Manufacturers of America (PhRMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) transparency commitments and EMA requirements.

The creation of documents intended for lay audiences and/or healthcare practitioners requires that the information be responsive to the audience's needs. Synchrogenix uses its proprietary, patent-pending, crowdsourcing solution that allows stakeholders to provide synchronous and asynchronous content and updates. This solution enables life science companies to not only create responsive content, but also understand cultural implications and advice from previously undiscovered experts.

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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