synchrogenix

A CERTARA COMPANY

Redaction and Anonymization

Advanced Anonymization

ClinGenuity Redaction Management Service

65+ EMA policy 0070 submissions

Redaction

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

ClinGenuity Redaction Management Service

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.

- The AI-powered solution is built on authoritative and proven natural language processing and recognition. As a result, our solution automatically and accurately identifies and marks sensitive information across thousands of pages and millions of words of documentation.
- Proven base rules for anonymization already defined and configured.
- Robust QC process of all anonymization deliverables prepared for regulatory authority submission.
- Expert consulting on regulatory policy and guidance, anonymization methodologies, reports, and agency support.

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.

- Sponsor can run API through Open Pharma or can host internally.
- Sponsor can run these functions collectively or as independent functions. These include but are not limited to auto-generation of Dataset Anonymization, Specification Reports, and Risk Scorecards.
- Run pre-defined anonymization rules or select pre-programmed methods for each data element on the fly!
- Alternatively, the sponsor can subscribe to the full Anonymization application and workflow.
- Synchrogenix Consulting services continues to provide oversight, QC of anonymized deliverables, and regulatory guidance.

We work closely with our clients to:

- Inform on choices and define critical parameters of the overall data transparency process.
- Review transparency guidance along with sponsor's confidentiality policies to determine what information is to be anonymized.
- Configure the system (based on established requirements), providing an end-to-end solution.
- Allow for the AI engine to create an automated output.
- Include legacy study reports, new study reports, and applicable submission documents.
- Work with scanned PDFs, converted PDFs, and Microsoft® Office documents.

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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