

Anonymization and Redaction

Moving Transparency and Disclosure Forward

Solutions that keep the concern out of compliance

Pharmaceutical companies and other sponsors of clinical trials are under increased pressures to disclose data and documents in accordance with regulations and requirements that include the European Medicines Agency (EMA) Policy 0070 and Health Canada Public Release of Clinical Information (PRCI).

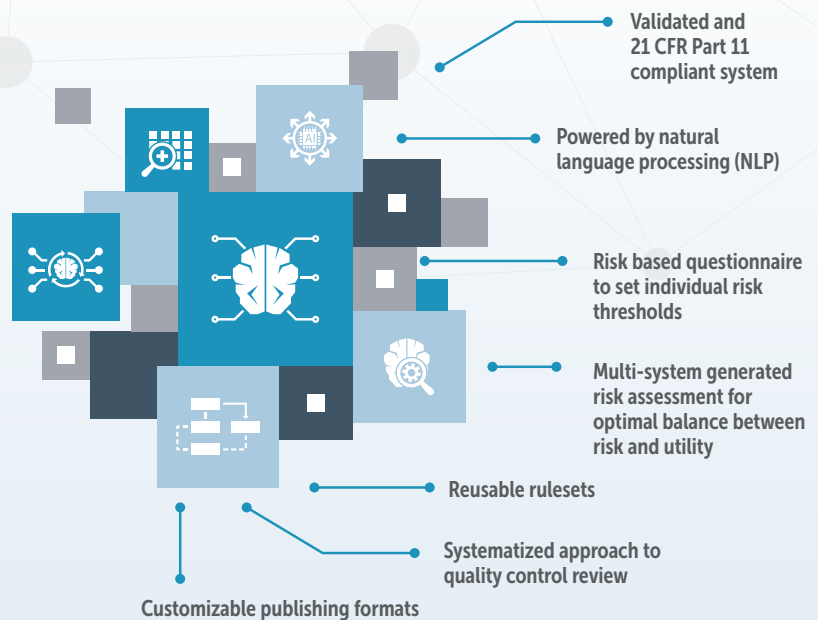
Are you concerned you're not in compliance?

As the leading technology and services provider in clinical trial transparency and disclosure, we provide technology-enabled advanced anonymization and redaction services for posting regulatory documents and clinical trial data in the public domain. These services include compliance assessment, consulting and project leadership, and remediation planning.

Data anonymization and redaction management powered by artificial intelligence

The Synchrogenix Redaction Management Service anonymization and redaction solution is supported by expert reviewers who ensure that trials with specific challenges, such as small populations or rare diseases, receive the customized approach they require. In addition, our experts assist sponsors with the authoring of anonymization reports.

Features of our anonymization tool



15 MILLION
report pages redacted to date

1 in every 3

published Health Canada PRCI submissions have been generated by *Synchrogenix, a Certara company*

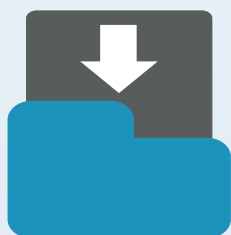
Technology paired with in-house statisticians

Recognizing the importance of optimizing the utility of your clinical data while still maintaining patient privacy, we employ our global team of in-house statisticians to assure your compliance with the evolving regulatory requirements for quantitative risk and advanced anonymization of trial data.

From clear-cut to more challenging thresholds and determinations based on population size and disease, we work with your team to determine the optimal approach.

“Thank you so much for providing all the documents required for the XXX NDS PRCI project, including the proposed redaction documents for personal information and confidential business information, anonymization report, and CBI control sheet.”

– Regulatory Director | Global biotechnology company



70+
EMA Policy
0070
submissions

Strategic Consulting Services

Our transparency and disclosure experts address sponsor-specific initiatives and risk tolerance while maintaining compliance according to established agency guidelines and industry watchdog measures.

- **Experienced consulting and project leadership to ensure that transparency requirements are met in the most optimal manner**
- **Preparation of remediation plans and creation of future robust processes, including policies, Standard Operating Procedures, and Work Instructions**
- **Routine and expedited clinical trial registration and results disclosure, including redaction of clinical trial protocols and statistical analysis plans**

CBI/CCI Identification

Preparing anonymized and redacted reports for regulatory agency submissions that remove Company Business Information (CBI) for Health Canada and Company Confidential Information (CCI) for EMA presents a major challenge for sponsors.

The ability to identify the intellectual property that sponsors want to protect versus what is already in the public domain is an extensive activity that calls on finite legal and regulatory resources within sponsor organizations. We address this for our sponsors by offering a unique consulting team that has expertise with both regulatory and legal backgrounds.

Our team of experts are able to:

- **Drive the identification process with your teams and take the lead in developing the criteria for a specific submission**
- **Manage the process for you, resulting in simplified review/approval**
- **Utilize our system to annotate the reports appropriately and develop an automated justification table/proposed control sheet**

Our process has saved sponsors a great deal of resources and frustration. Additionally, sponsors have seen a reduction in agency review comments of your CBI/CCI.