CERTARA | SYNCHROGENIX

Transparency and Disclosure

Meet and exceed compliance requirements

Enhance engagement. Meet requirements. Maintain 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).

As the leading technology and services provider in clinical trial disclosure and transparency we provide expertise and technology-enabled services not only to meet transparency and disclosure requirements but also to enhance the engagement of study participants, their caregivers and healthcare professionals, and the general public.

Enhancing Engagement

- Patient engagement with Podium
- Plain Language Summaries

Meeting Requirements

- Assessment of your current compliance
- Remediation planning and preparation
- Redaction and data anonymization

Maintaining Compliance

- Strategic consulting and project leadership
- Global clinical trial postings and results disclosure

Accurate and efficient global clinical trial postings and results disclosure

Using a proven methodology, we've supported sponsors with thousands of trial postings to global disclosure databases, including Clinicaltrials.gov, EudraCT, China CTE, and other applicable worldwide registries.

Data anonymization and redaction management powered by artificial intelligence

The Synchrogenix Redaction Management Service artificial intelligence-powered 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.

15 MILLION
report pages redacted to date

Certara.com/Synchrogenix

Engage with patients via Podium

Using our secure, easy-to-use Podium platform, sponsors can receive valuable feedback and comments from patients and advocacy groups throughout the clinical trial process within specified therapeutic areas on:

- **Protocol feasibility**
- **Informed consent forms and patient summaries**
- **Plain language summaries**

Ensure that study participants are informed with plain language summaries

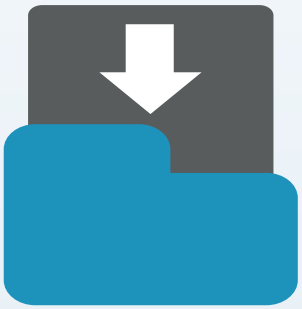
Although not yet a regulatory requirement for the FDA or EMA, it is expected that the EMA will require all clinical trial sponsors to prepare a summary of the results of every clinical trial written in language understandable to the general public by December 2021.

Having authored more than 200 plain language summaries to date, our medical writers produce plain language summaries in the voice and advocacy of the patients' interests, effectively and efficiently, while maintaining scientific accuracy.

> **"Patients want to learn everything they can about their health.** Unfortunately, much of the available literature is so complex that it is not usable for patients. Synchrogenix is working with Rare Patient Voice patients to incorporate their voices into clinical trial summaries. This is a wonderful way to ensure that important scientific data is available to patients in a clear and understandable format."
>
> – **Pam Cusick,**
> Vice President, Business Development
> Rare Patient Voice

1 in every 3

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



70+

EMA Policy 0070 submissions