synchrogenix

A CERTARA COMPANY

Transparency and Disclosure in Clinical Trials

Mitigating risk and ensuring compliance across all publically disclosed text and data

The issue of transparency and disclosure of clinical trial data has been growing in importance over the past few years. Disclosing clinical trial information and creating transparency around the data are key steps toward increasing trust between the public and the industry. Increased transparency regarding data about ongoing research could spur new products or therapeutic approaches and potentially avoid unnecessary trials.

- The European Medicines Agency (EMA) Policy 43, *Access to Documents*, adopted on December 1, 2010 provides a process by which individuals can request access to all EMA business-related documents. The EMA has the responsibility of redacting documents for approved requests, however if clinical reports are requested, the EMA may provide sponsors with a proposed redacted version of the document about which the sponsor can provide feedback prior to the documents release to the requestor.
- The EMA Policy 70, *Publication of Clinical Data for Medicinal Products for Human Use*, was adopted on January 1, 2015. Under this new law, the EMA will make all clinical study reports available that support an approved marketing authorization.
- On January 14, 2015, the Institute of Medicine (IOM) released its report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, which outlines principles and a practical framework, including recommended time periods, for the responsible sharing of clinical trial data.
- The US Food and Drug Administration (FDA), along with the National Institutes of Health, are also addressing the need for improved transparency and disclosure. The 2012 FDA Safety and Innovation Act requires this issue to be addressed.
- The pharmaceutical industry's largest trade organizations, Pharmaceutical Research and Manufacturers Association (PhRMA) in the US and European Federation of Pharmaceutical Industries and Associations (EFPIA) in the European Union (EU) are committed to Principles for Responsible Clinical Trial Data Sharing. Under these principles, companies agree to enhance public access to clinical study information for any submission following a January 1, 2014, US or EU approval.

> "The adoption of this policy sets a new standard for transparency in public health and pharmaceutical research and development. This unprecedented level of access to clinical reports will benefit patients, health care professionals, academia and industry."
>
> – Guido Rasi, EMA
> Exec. Director, Policy 70

> Greater data sharing could enhance public well-being by accelerating the drug discovery and development process, reducing redundant research, and facilitating scientific innovation.
>
> – Institute of Medicine

> Reporting of results of human studies of new treatments to the federal government's ClinicalTrials.gov database from academic institutions arrived late or not at all 90 percent of the time, compared with 74 percent for industry.
>
> – 'Failure to Report', Charles Piller, STAT News, December 13, 2015

- The industry group TransCelerate BioPharma Inc. has published several reports outlining its commitment to enhancing public health and medical and scientific knowledge through the sharing and transparency of clinical trial information, including:
  - August 2014, *Clinical Study Reports Approach to Protection of Personal Data*
  - April 2015, *Data De-identification and Anonymization of Individual Patient Data in Clinical Studies—A Model Approach*
  - December 2015, *Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results*

Synchrogenix Transparency and Disclosure Services

Synchrogenix, a Certara company, provides services, technology, and expertise to meet transparency and disclosure requirements. Synchrogenix produces anonymized clinical documents, lay summaries, as well as supports protocol registration and disclosure of study results. These documents are created according to established policy guidelines and customized to address sponsor-specific business rules to address compliance and consistency requirements. Our unique artificial intelligence (AI)-enabled technology is the most effective and efficient approach to mitigate risk for meeting data transparency requirements. This technology is effective across our entire suite of services and can be employed to meet each company's business objectives.

Policies 43 and 70—ClinGenuity Redaction Management Service (CRMS)

We offer the only AI-enabled redaction solution in the marketplace to automatically identify and redact protected personal data (PPD) and company confidential information (CCI) with more than 99% accuracy.

- The Synchrogenix CRMS solution is fully compliant with the EMA Policy 43 and TransCelerate.
- 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 for redaction-sensitive information across thousands of pages and millions of words of documentation at accuracy levels that manual options simply cannot match.

We work closely with our clients to

- Define criteria around several aspects of the overall process.
- Review transparency guidance along with company-confidentiality policies to determine what information is to be retained versus what is to be redacted.
- 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 submission documents.
- Work with scanned PDFs, converted PDFs, and Microsoft® Office documents (the system can accept converted Microsoft Office documents, but it does not accept these documents for redaction outright—they must be in PDF form for redaction).

Lay summaries

- Synchrogenix in partnership with the Center for Information and Study on Clinical Research Participation (CISCRP), provides clinical trial participants with high-quality, written summaries of their trial's results. Lay summaries provide patients and others with a summary of the complex scientific explanation of the clinical research project.
- Lay summaries support PhRMA and EFPIA transparency commitments and pending European Union requirements.

Clinical trial disclosure

- Synchrogenix provides services to accurately and efficiently assess current sponsor compliance on ClinTrials.gov and EudraCT systems, establish a remediation plan, establish future processes and complete clinical trial registrations and disclosures.
- Our uniquely trained writers and editors lead and operationalize the registration and disclosure component of clinical trial data to meet transparency requirements.

The Synchrogenix Difference – Global operations and accountability

- Synchrogenix is one of the largest regulatory/medical writing consultants in the world, with 100 in-house writers, globally, and has the ability to leverage a network of more than 200 additional experienced writers.
- Synchrogenix maintains the highest standards in the industry, and all of our in-house writers and editors must meet these requirements as part of our hiring and onboarding process.
- Our expertise in regulatory and medical writing supports US, EU, and broader, global strategies and filings.

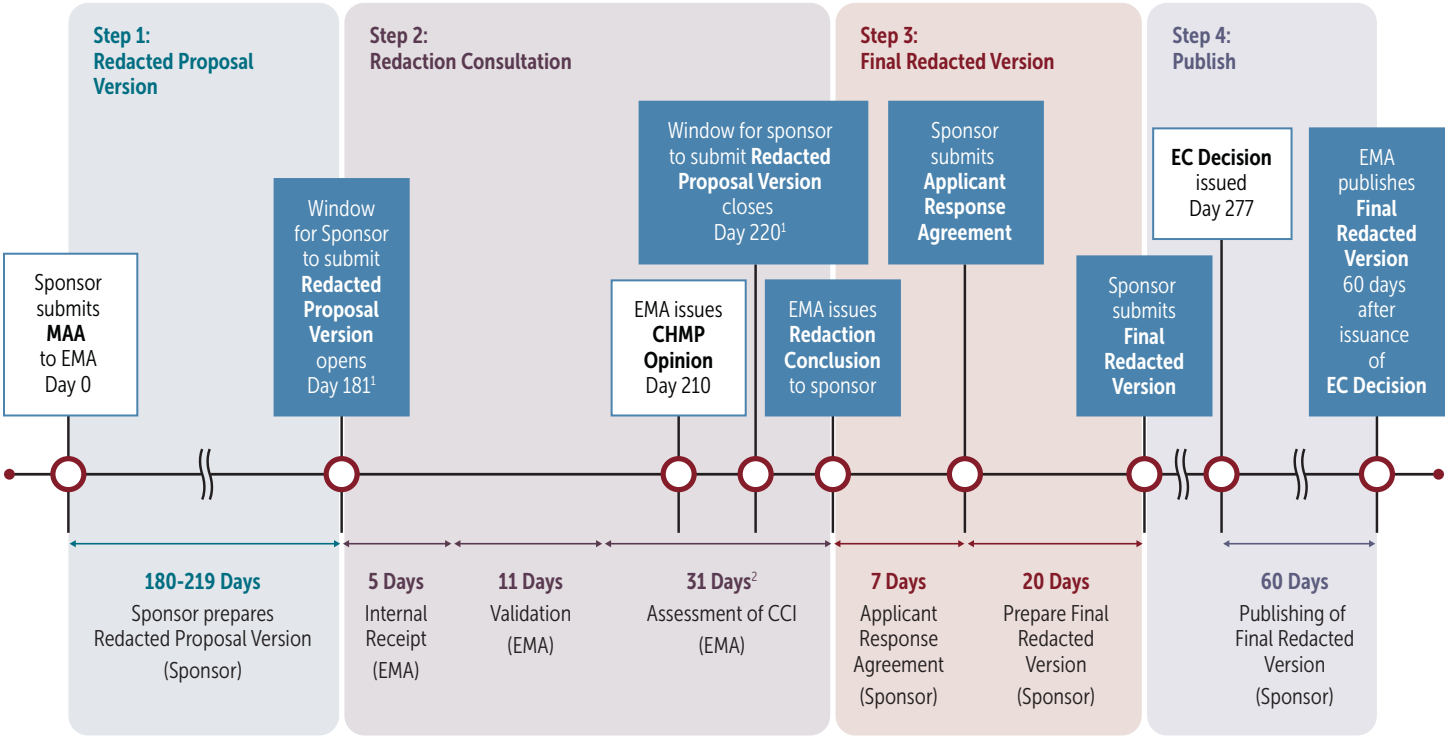
Use of Artificial Intelligence technology

- We offer the only AI-enabled solution to support the clinical and drug development market. This technology is the most effective and efficient approach to mitigate risk for meeting data transparency requirements.
- This solution automatically analyzes words, phrases, and parts of speech for automated output at more than 99% accuracy.
- Our solution is exact, fast, and requires little-to-no sponsor management, freeing up your team to concentrate on more strategic activities without the distraction of non-compliance and without having the additional cost burden compared with manual options.

Holistic, forward-planning approach

- Synchrogenix consults with sponsors to address any immediate compliance needs but also to align with larger company goals and future planning. By asking the right questions during the front end meetings, we work together to assess the right process, tools, and resources to get the job done.
- Along with our parent company, Certara, our experts are driving technology-enabled solutions to the life science community to address critical decisions in drug development and ethical obligations to all stakeholders.
- Through our relationships with 1200 biopharmaceutical companies, key regulators with the US, EU, and Japan regulatory agencies, and our participation in consortiums and associations, we anticipate suggesting changes, influenced by global regulatory policy, that enable sponsors to deliver safe, new therapies to patients.

EMA Policy 70 Timeline



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.

For more information visit www.certara.com or email sales@certara.com.

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