

# Overcoming confidential information challenges faced by study sponsors today

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## Abstract

As health authorities aim to increase clinical trial transparency and visibility to the public, pharmaceutical manufacturers are facing new pressure points. New regulations require the disclosure of clinical trial application data, many of which contain sensitive and confidential information about company intellectual property including, but not limited to, its manufacturing methods, drug composition, names of suppliers, and future development plans. Many manufacturers are examining their processes to minimise references to this confidential data during the document authoring process and how they track and identify confidential information throughout the study lifecycle. This has created a catalyst for medical writing, transparency, legal, and regulatory teams to collaborate and enhance their processes to minimise disruption to the trial approval process while embracing the opportunities to share more with the public.

## Introduction

Policies and regulations such as Health Canada Public Release of Clinical Information (PRCI), EMA's European Union Clinical Trial Regulation (EU CTR) and EMA Policy 0070 are exposing operational challenges for pharmaceutical and biotechnology manufacturers in the identification, tracking, disclosure, and management of confidential information (CI); specifically known as confidential business information (CBI) by Health Canada<sup>1</sup> and commercially confidential information (CCI) by the EMA<sup>2</sup> throughout the clinical lifecycle. Note that throughout this article the

term CI will be used.

While these policies and regulations require a significant amount of information pertaining to the trial itself be disclosed, including the trial results, there is a line drawn regarding information that remains proprietary to the manufacturer.

## Health Authority expectations

### Health Canada's PRCI

The PRCI initiative is designed to increase transparency in the drug and medical device approval process while protecting CI. By making clinical information publicly available, Health Canada aims to promote research and innovation.

Health Canada states the following regarding its definition of CI:

- "CBI", in respect of a person to whose business or affairs the information relates, means – subject to the regulations – business information:
  - That is not publicly available
  - In respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available
  - That has actual or potential economic value to the person or their competitors because it is not publicly available, and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

Sponsors can request, with justification, certain information be redacted if they believe it meets the criteria for confidentiality. The justification of certain redactions may require the manufacturer to draw on information within their internal corporate plans (e.g., future development of new indications based on secondary outcome data). Consequently, Health Canada requests that the manufacturer submit an annotated version of all clinical information in scope of publication with any and all proposed redactions highlighted for

Confidential information is information contained in the clinical trial which is not in the public domain, or publicly available, and where disclosure may undermine the legitimate economic interest or competitive position of the owner of the information.

regulator review. Any text the manufacturer proposes to redact must remain readable, and all proposed redactions should be accompanied by specific and detailed justification recorded using the "Proposed Redaction Control Sheet" in .CSV format.<sup>1</sup>

### EMA

The EMA considers CCI as any information contained in a clinical trial application or provided during the trial life cycle that is not in the public domain or publicly available, and where disclosure may undermine the legitimate economic interest or competitive position of the clinical trial sponsors or marketing authorisation applicants/holders.<sup>3</sup>



The EU CTR expects the following regarding CI:

- Sponsors may indicate CCI in non-public version documents for the health authority and member state reviewer's awareness.
- The EMA may request additional information to support the justification for confidentiality.
- The sponsor may redact CCI from public version (known as "for publication") documents posted to the Clinical Trials Information System (CTIS).

Implemented in 2015, EMA's Policy 0070 was suspended, with certain exceptions, in December 2018, due to Brexit and eventually COVID-19. EMA has since relaunched Policy 0070 with a gradual rollout from September 2023 applicable for new active substance approvals, negative and withdrawn applications.<sup>4</sup> The re-launch includes certain changes to the policy including the use of a revised anonymisation report template and proactive notification of expected CI prior to the draft submission. The second phase of the re-launch is likely to take place in 2024 with details pending announcement from EMA.



## EU CTR operational challenges observed by pharma manufacturers

### 1. Regulatory rejections

Proposed CI by study sponsors has historically been tracked by Health Canada and EMA at a 65%<sup>5</sup> and 60%<sup>6</sup> rejection rate respectively due to:

- Information marked as CI by the sponsor that is already in the public domain
- Information marked as CI by the sponsor that is not innovative
- Information marked as CI by the sponsor that is in the public interest

### 2. Ownership and authority

Consensus decision regarding CI references in a trial document for a given asset, programme and/or study is a common challenge within global pharmaceutical teams today. Typically, the identification of CI is a collaborative effort led by intellectual property (IP) legal, medical writing, regulatory, safety, clinical and non-clinical teams, and transparency and disclosure teams. With no single owner, decision making in some organisations has proven difficult while balancing protection of the information with the potential risk of delays due to regulatory push back.

### 3. Tracking CI throughout the clinical lifecycle

Accurate tracking of CI pertaining to any given asset, programme, or study can be challenging due to:

- Changes in classification of CI over time
  - Awareness of publications in the public domain that may refer to specific references once deemed confidential
  - Consistency across global trial registries; specifically what information is being disclosed on each

### Easing the CI burden

The following operational considerations may assist medical writers and cross-functional colleagues in setting a repeatable and scalable business process for identifying, managing, and tracking CI consistently across studies. These recommendations are especially applicable for those pharmaceutical manufacturers submitting studies via CTIS, the EMA system used to facilitate trial applications and disclosures in Europe.

1. CCI procedures defined specifically for your organisation and team structure can play a significant role in streamlining CI related decisions, process, and outcomes

- Implement an authoring minimisation initiative; include references to CI that is required and minimise repetition of those references within the document
  - Define a consistent deferral strategy and decision process
  - Document the hand-offs between teams, CRO, redaction service provider
  - Set expected turnaround times for document redaction including review and approval cycles and final version updates
  - Clearly define roles and responsibilities regarding review and approval of CI across functional team members
  - Document resource mobilisation and action plans for Requests for Information (RFIs) e.g.; RFI response PI
2. Tracking all CI in a centralised "library"
    - Create a centralised listing of CCI per asset, programme, and/or study
    - Include cross-functional team leads from safety, manufacturing, IP legal, corporate librarian, and transparency in reviews and approvals
    - Set maintenance procedures for tracking changes over time. What is CI today may not be tomorrow
    - Refer to the library during the document authoring process to support minimisation techniques
  3. Finalise internal standards and authoring procedures
    - Revise document authoring templates to include minimisation expectations, excluding unnecessary references to CI wherever possible when authoring clinical documents
    - Maintain awareness of current CI at all times during the authoring process
    - Categorise documents into groupings for prioritisation, review, and approval:
      - **Group 1** – "Dense" documents that typically contain the most references to CI such as the protocol and investigator brochure
      - **Group 2** – Other documents with fewer references to CI, e.g.; PI CV, proof of insurance, proof of payment
      - Define common use scenarios for regulatory document management system(s) which may support your review and approval processes

4. To prevent unnecessary or excessive redactions which may expose inadvertent errors or missed redactions, the following minimisation techniques are recommended:
  - **DO** include **ONLY** the content that is required to meet the document's objective and nothing additional
  - **DO** highlight or designate CI in the document at the time of authoring for review by the transparency and/or redaction team member
  - **DO NOT** reference CCI in the document's Table of Contents, body, header/footer, and table titles
  - **DO NOT** duplicate content; instead include cross-references such as, "refer to Section A", thereby decreasing the number of instances of CI within a document(s).
  
5. Cross-functional team members in regulatory, safety, manufacturing, IP legal, and transparency, must share a common understanding of what CI is (and is not):
  - Demonstrate practical examples using previous public version documents
  - Explain/illustrate the justification and decision process for those examples
  - Include positive (is CI) and negative (is not CI) examples and explain why
  - Review the most current library with cross-functional team leads

**Overcoming challenges with redacting documents**

The task of redacting CI from regulatory documents may be laborious and error prone if the proper tools and technology solutions are not utilised. Study teams may run into challenges meeting tight turnaround times especially when faced with processing multiple documents in a short period of time to meet the document submission deadlines and trial approval schedule. Use of a purpose-built redaction solution for your organisation can help with expediting and streamlining the redaction, review, and approval process. Examples of capabilities that can accelerate your redaction processes are as follows:

- Apply study-specific saved searches to identify and redact specific terms and references within a document.
- Apply saved searches to one or more documents simultaneously.
- Enable collaboration with team members directly in the document to avoid non-secure



messaging and emailing of sensitive files and file version control issues.

- Generate a systemic audit trail to view all redaction marks and justifications for one or more documents.
- Use integrated project management tracking to report progress, anticipated redaction completion dates, and management visibility.

**Disclosures and conflicts of interest**

The author is employed by Real Life Sciences, which provides anonymisation software and services discussed in this article. The author declares no conflicts of interest.

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As CEO, **Elliot Zimmerman** leads the team at Real Life Sciences in advancing clinical trial transparency. Elliot retains a pharmaceutical and clinical technology background with experience as COO at goBalto, Inc. prior to acquisition by Oracle in 2018. Elliot serves on the Steering Committee of CRDSA (Clinical Research Data Sharing Alliance).