



Protecting Commercially Confidential Information (CCI) Under the EU Clinical Trials Regulation

PHUSE White Paper Update — March 2026

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White Paper: Scope & Problem Statement

Purpose

- Practical guidance for sponsors to identify, manage, and protect Commercially Confidential Information (CCI) in EU CTA submissions via CTIS

The Challenge

- EU CTR mandates early public disclosure of CTA documents — protocols, ICFs, and patient-facing materials are now published at trial onset
- Revised CTIS transparency rules (Oct 2023) removed deferral mechanisms — redaction is now the only tool to protect CCI
- Sponsors must balance regulatory transparency with IP protection across multiple jurisdictions and trial lifecycle stages

Scope

- CCI protection in Part I and Part II CTA documents disclosed through EU CTIS
- Covers redaction processes, CCI libraries, stakeholder engagement, and AI-enabled solutions

Key Recommendations for Sponsors

1. **Draft with disclosure in mind** — Adopt a “disclosure-first” mindset; limit CCI inclusion from the start in protocols, ICFs, and patient-facing documents
2. **Establish a systematic redaction process** — Define stakeholders, map workflows, and align with EU CTR assessment timelines (60–106 day window)
3. **Build dynamic CCI libraries** — Maintain a centralized library tracking CCI status across the product lifecycle; track when CCI enters the public domain
4. **Leverage AI-enabled solutions** — Use LLMs to support CCI identification and redaction while maintaining human oversight and security controls
5. **Align cross-functional teams** — Engage regulatory, legal, medical writing, clinical development, and partner organizations around a unified CCI strategy

Next Steps & Call to Action

This white paper will be open for public comments by end of March 2026

1. Review

Read the white paper and assess how the recommendations apply to your organization's CCI practices



2. Comment

Submit your feedback during the public comment period opening by end of March 2026



3. Engage

Share with your teams and join the PHUSE working group to shape future best practices



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