EU CTR Feedback

Dear PHUSE Data Transparency Working Group,

Thank you for the opportunity to reviewWP-119: Protecting Commercially Confidential Information (CCI) While Complying with the European Union Clinical Trials Regulation 536/2014. The paper provides a strong operational foundation, and I appreciate the clarity with which the authors describe the revised CTIS transparency rules, including the observation that "documents supporting Phase I studies are likely to contain more CCI" and that sponsors must "exercise caution regarding the extent of redaction applied" to avoid rejection by Member States.
Below are my comments intended to strengthen the paper's practical utility and long-term value for sponsors.

1. Strengthen the Conceptual Architecture of CCI Classification
The paper provides helpful examples of CCI (Table 3) and non-CCI (Table 4), but sponsors would benefit from a more structured decision model for classification.
For example, the document notes that "CCI classification varies by sponsor, by study, and throughout the dynamic lifecycle of a molecule," yet the paper does not offer a harmonised framework for lifecycle-based classification.

Recommendation:
Introduce athree-tier CCI decision architecture:
Tier 1 — **Patent-sensitive information** (early-phase, novel mechanisms, exploratory endpoints)
Tier 2 — **Competitive-position information** (vendor-specific methods, adaptive design logic, future development plans)
Tier 3 — **Operationally sensitive information** (supply chain, manufacturing specifics, proprietary COAs)
This would help sponsors apply consistent logic across programs and reduce Member State variability.

2. Expand the Redaction Model into a Metadata-Driven Workflow
The paper describes redaction as the primary mechanism for CCI protection and includes a process diagram (Figure 1). However, the current approach is document-centric, not metadata-centric.
Given the complexity of CTIS submissions, sponsors increasingly require:

1. reusable metadata tags for CCI categories
2. structured redaction rules
3. automated detection of sensitive content
4. traceability across versions and RFIs

Recommendation:
Add a section describing a **metadata-anchored redaction model,** where each CCI element is tagged at source (protocol, SAP, ICF) and propagated through downstream documents. This reduces rework, improves consistency, and supports automation.

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3. Provide More Guidance on "Borderline" CCI Categories
The paper acknowledges that Member States may be inconsistent in their review of redactions and that "CCI is assessed on a case-by-case basis."
Sponsors struggle most with ambiguous categories such as:
1. exploratory endpoints
2. adaptive design elements
3. novel COAs
4. vendor-specific methodologies
5. future development plans

Recommendation:
Include a decision **tree** or **case examples illustrating** how to classify borderline items under the revised transparency rules.

4. Add Forward-Looking Guidance on Automation and AI-Assisted Redaction
The paper briefly notes the "absence of robust technology-enabled redaction tools," but does not elaborate.
Given the volume and velocity of CTIS submissions, sponsors increasingly rely on:
1. NLP-based CCI detection
2. automated redaction pipelines
3. audit-ready redaction logs
4. version-controlled CCI libraries (Figure 3 hints at this but could be expanded)

Recommendation:
Add a subsection on automation **readiness**, including how sponsors can structure documents and metadata to support future AI-enabled redaction workflows.

5. Strengthen the Global Harmonisation Context
The Background section compares EMA, FDA, PMDA, and Health Canada requirements, but the paper could better articulate how sponsors should harmonise **CCI strategy across jurisdictions**.
For example, the paper notes that EMA Policy 0070 requires "detailed, specific, and robust justification for each proposed CCI redaction," whereas the EU CTR does not. This difference creates operational divergence.

Recommendation:
Add a short section on **cross-framework harmonisation**, helping sponsors avoid duplicative work and inconsistent CCI positions across global submissions.

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6. Expand the Risk Section with Practical Scenarios
The paper correctly notes that inadvertent disclosure can jeopardise patents and competitive positioning. The statement that "CCI will remain publicly accessible until the retraction is processed" is particularly important.

Recommendation:
Add 2–3 anonymised case scenarios illustrating:
1. how inadvertent disclosure occurred
2. how it was detected
3. how long retraction took
4. what irreversible consequences resulted
This would elevate the practical value of the paper.

7. Clarify the Role of CCI Libraries and Governance
The paper mentions the "lack of CCI libraries and processes for library maintenance," and Figure 3 shows a conceptual library.

Recommendation:
Expand this into a governance **model**, including:
1. ownership
2. update cadence
3. cross-functional review
4. integration with protocol templates
5. alignment with legal/IP teams
This would help sponsors operationalise the concept.
Thank you again for the opportunity to review this important White Paper. The revised CTIS transparency rules represent a major shift in the regulatory landscape, and this document provides a strong foundation. The enhancements suggested above aim to strengthen the conceptual architecture, improve operational clarity, and support sponsors in implementing scalable, defensible CCI protection strategies.

The comments above were submitted by Yogesh Kumar Gupta as part of the public review of this paper.