P3 – Medical Writers: A Pivotal Role in Leading Teams to Compliance with EU CTR Transparency Requirements

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INTRODUCTION

Transparency is at the heart of the EU Clinical Trial Regulation (Regulation No. 536/2014) and public interest in clinical trial data is growing. Under the regulation, documents that comprise the clinical trial application are subject to public disclosure. To protect the competitive interest of the sponsors, the Regulation introduces the concept of protection of commercially confidential information (CCI) as a ground to justify confidentiality of all or part of the data. Medical Writers are central to the preparation of documents impacted and are, therefore, perfectly placed to consult to address EMA's transparency requirements.

METHODS

The team developed a process to guide clinical study teams through the identification of CCI in clinical trial documents. The main challenges and lessons learned based on the experience gathered from 11 development programs over an 18-month period are presented.

RESULTS

The assessment of what constitutes CCI requires a case-by-case analysis and depends on the stage of the clinical development program (and medicinal product). The Medical Writer's perspective of document development helps direct study teams to minimize the number of redacted concepts, which can evolve over time. Commercially confidential information requires robust rationale to provide a case for supporting its redaction.

CONCLUSIONS

Identification of CCI at document conception, and engagement and collaboration of cross-functional teams led by Medical Writers are key to a successful outcome. These practices expedite the redaction process and highlight, and potentially minimize, the level of CCI at the earliest opportunity.