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Plagiarism In Clinical Evaluation Reports (CERs) **What To Look Out For**

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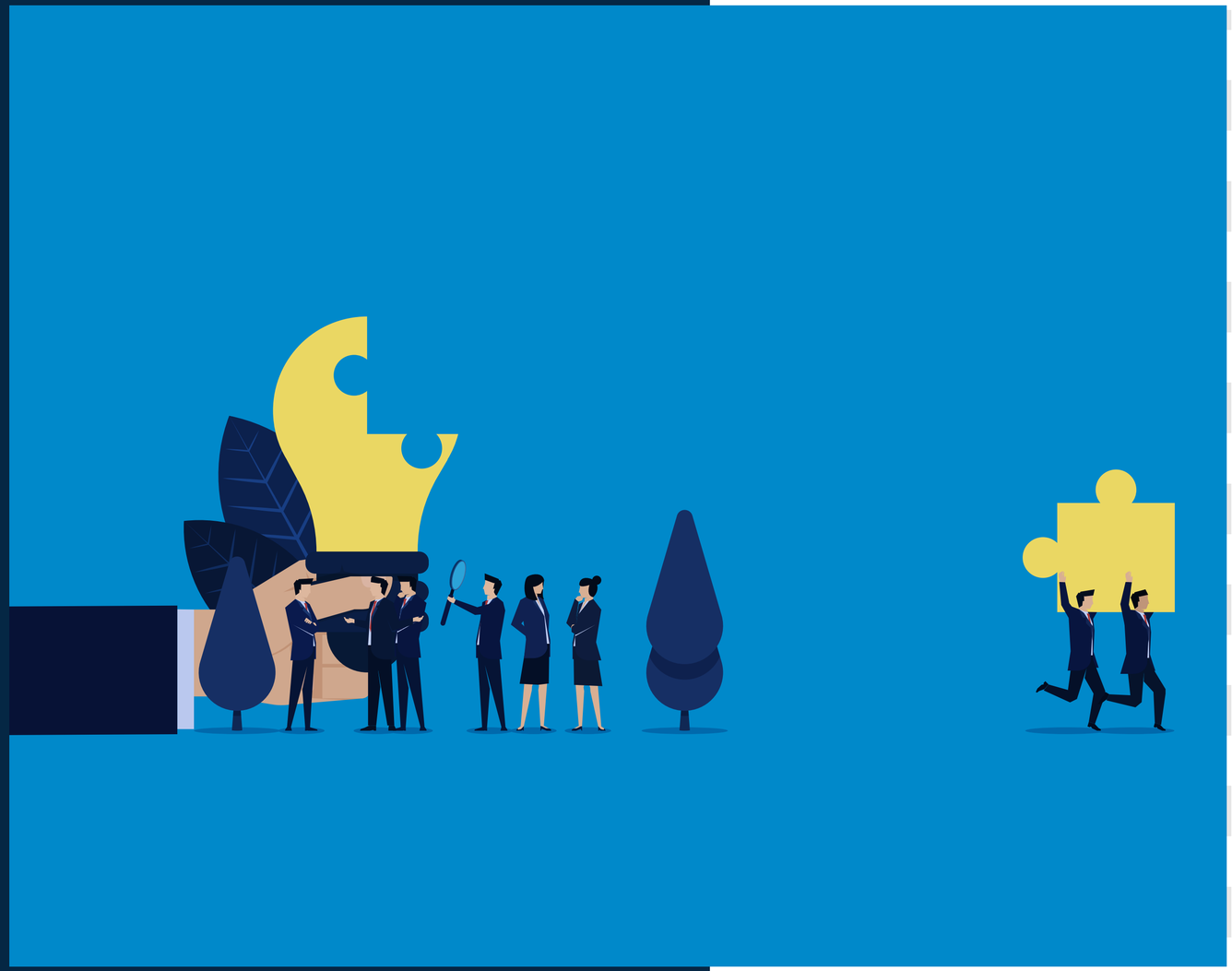
Plagiarism can have a detrimental effect in scientific/medical research, as it triggers both disreputation and depreciation but in the case of regulatory writers involved in the production of CERs, plagiarism accusations could also result in major non-conformances and obsolescence of the evidence provided to support conformity to essential requirements.
But is it possible to be in a situation where a regulatory writer will commit plagiarism in a Clinical Evaluation Report?

In this eBook, we will examine guidelines for regulatory writing and documents, incidences and causes of plagiarism, as well as what to look out for, if in doubt.



The preparation of Clinical Evaluation Reports (CERs) is a highly demanding task that prerequisites knowledge of Regulations, outstanding writing and research skills, as well as the ability to critically appraise scientific information.

Given the legal aspects and restrains of CERs, **regulatory writers are not requested to present their own original work**, but rather collect/appraise all available data from different sources (manufacturer, authorities, medical literature, etc.) and prepare a critical, concise assessment according to relevant guidelines and/or Regulations (e.g. MEDDEV, MDCG, EU-MDR 2017/745 etc.), while remaining neutral and unbiased[1].

Although there are guidelines and statements describing the appropriate role of medical writers during the development of medical and scientific publications, including articles in peer-reviewed journals and presentations during congresses, there is no such guidance set in stone for plagiarism in CERs.

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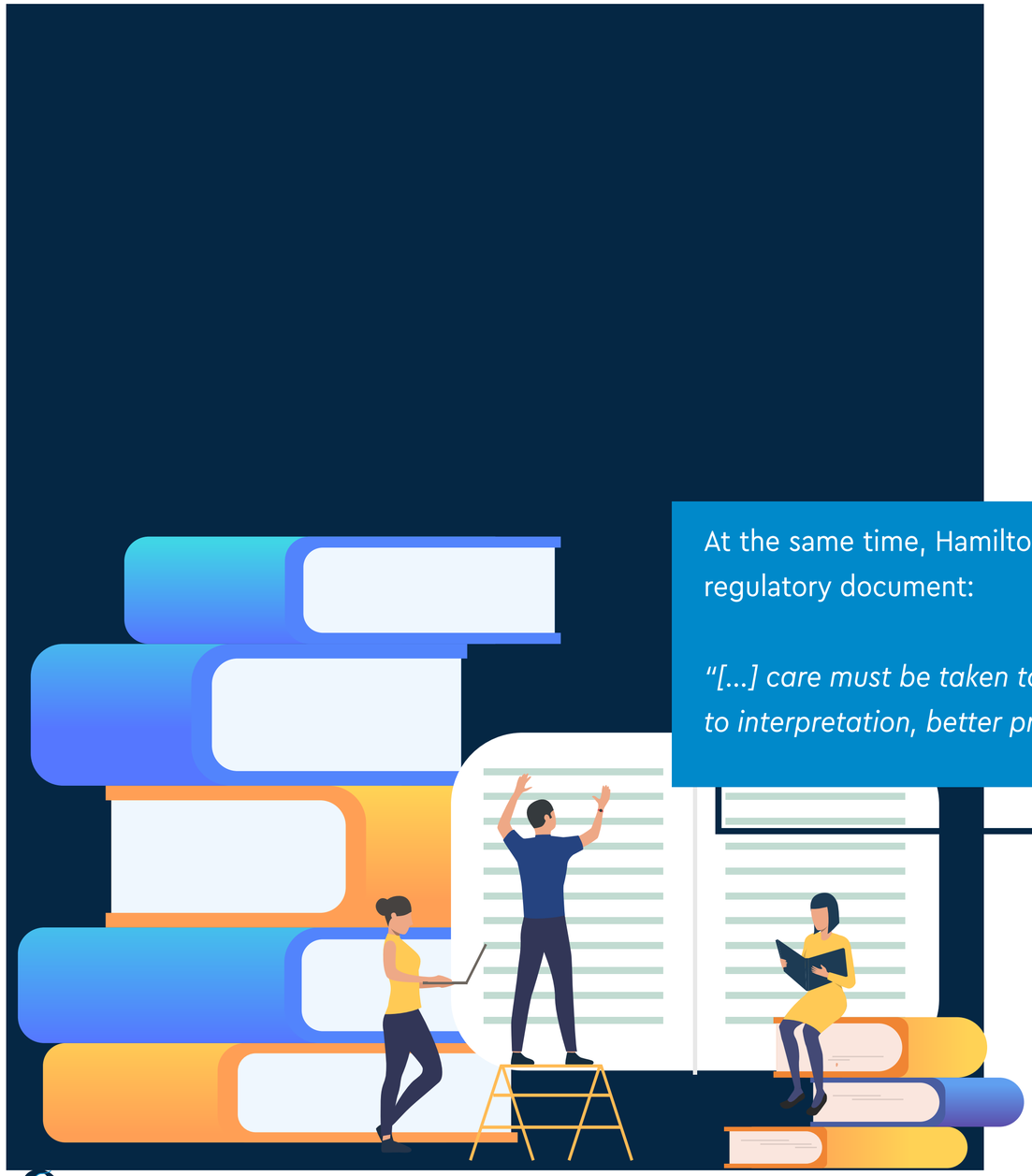


As regulatory writers, we are constantly looking for guidelines to follow during the production of documents. MEDDEV 2.7/1 Rev. 4 states that a CER should include a comprehensive literature review with full identification of articles and products discussed. The appraisal of these data should be thorough, objective, systematic and unbiased and the evaluators are expected to set up an appraisal plan that describes the procedure and eligibility criteria used. However, MEDDEV guidance provides no explicit instructions for regulatory writers on **whether copy-pasting from scientific documents should be avoided** – something that in scientific publications would clearly be marked as plagiarism..

At the same time, Hamilton[2] does argue that it is better to copy-paste than to provide inaccurate information in the regulatory document:

"[...] care must be taken to cross-reference only accurate original material. If accuracy is in question or text is open to interpretation, better practice is to include abstracted unambiguous information directly in the CSR text."

So the question remains: what is the rule when writing CERs or other regulatory documents and could copy-pasting of original material be **interpreted** as plagiarism?

Within the scientific writing context, **plagiarism is a form of scientific misconduct related to the unacknowledged presentation or exploitation of work and ideas of other researchers as one's own**. Plagiarism should be distinguished from other expressions of scientific fraud/misconduct, such as data fabrication, data falsification and deception during conduct of a trial and/or an experiment[3–5].

Although the incidence of plagiarism varies significantly from source to source, there is increasing evidence we are dealing with an alarmingly increasing form of mal-practice[6–8]. The recently published "Retraction Watch" database, which includes more than 18,000 retracted papers and conference abstracts dating back to the 1970s, has allowed the Science magazine to analyze more than 10,000 retracted articles[9].

This highlights that lack of ethical awareness, poor understanding of both scientific writing guidelines and the repercussions of committing plagiarism, as well as poor language proficiency and limited experience can easily result in lack of writing confidence and, therefore, to plagiarism in order to produce a "publishable" work.

Added to the above, the "Publish or Perish" effect[10, 11], often holding hands with the "Chaperone effect"[12], exert a substantial amount of pressure on researchers that are struggling to rise from "anonymity" and gain popularity and prestige – which are often attached to funding and academic ascent.

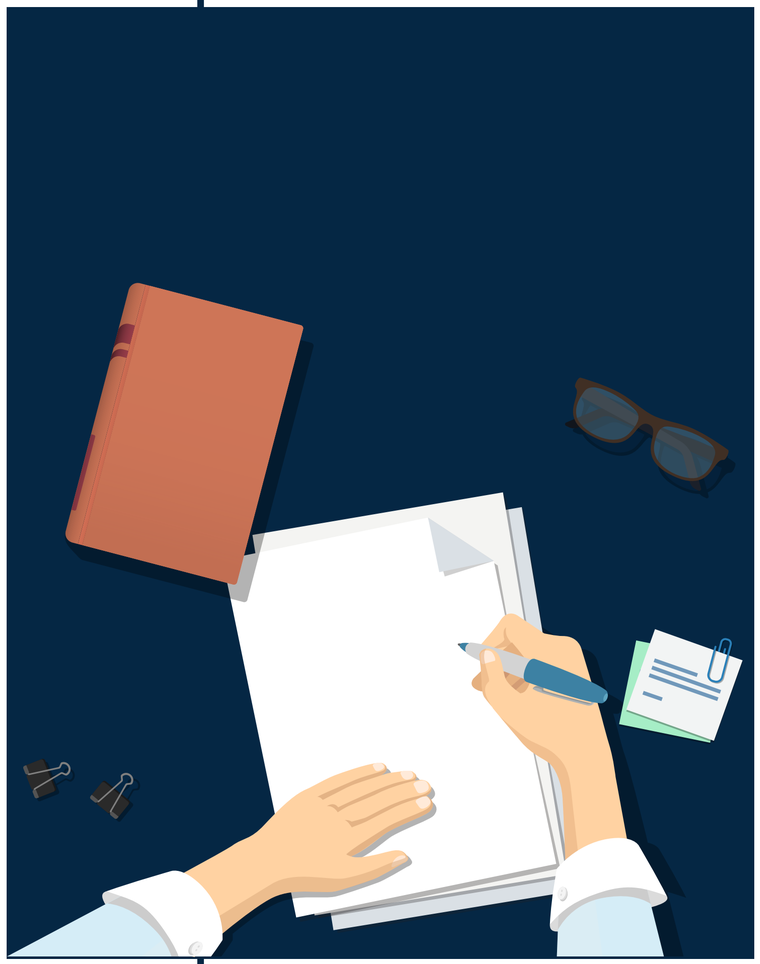
However, a **regulatory writer has no personal benefit from the CER** in the sense that the CER is a strictly confidential regulatory document, which cannot be used by the writer as proof of published work.

The primary role of regulatory writers is not to present original work, but to collect and appraise **all** available data from different sources (manufacturer, authorities, medical literature, etc.) in order to prepare a critical, concise interpretation to be used as evidence of the continued safety and performance of a medical device.

The project assigned to the regulatory writer is not complete until an exhaustive, critical analysis of data has been performed. Unbiased referencing and unrestricted access to bibliographical resources cannot account for plagiarism, also because clinical data is appraised and assessed, based on data contribution, data suitability and levels of evidence in order to prove conformity with legal requirements.

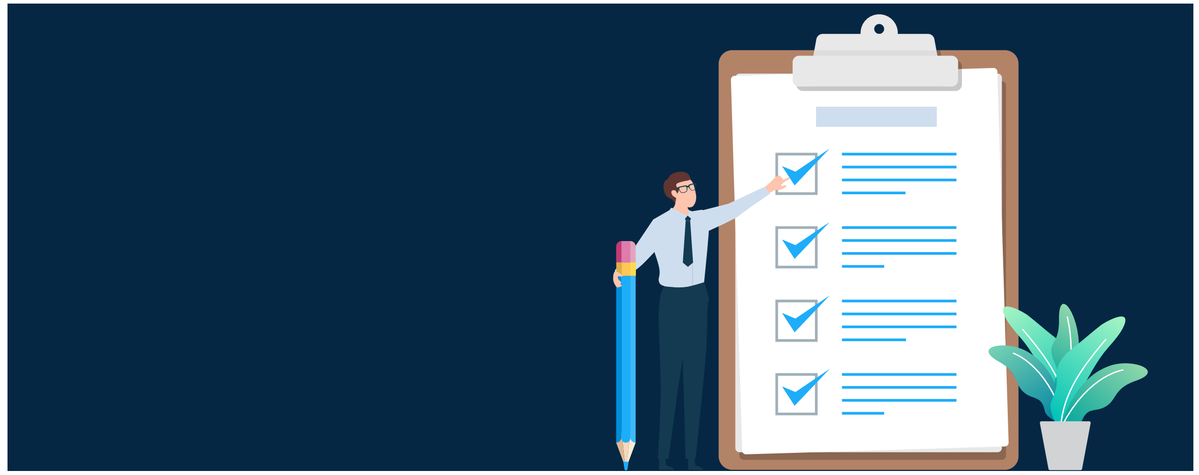
Even when a regulatory writer cites their own article(s) in a CER, this will not be registered to their citation record, because **CERs remain strictly confidential at all times**. In any case, withholding information and/or citations within the context of a regulatory document, is extremely difficult, if not impossible, as the final product is subject to revision (AND approval) by the authorities and the manufacturer.

It is more likely for regulatory writers to detect plagiarism given their unlimited access to data and the systematic appraisal of clinical literature. Needless to mention that language and writing proficiency excludes CER regulatory writers from being plagiarism candidates, as they are selected via a scrutinised process that ensures their ability to manage both linguistic and technical aspects of a CER.



Since there are no explicit guidelines on plagiarism in CERs, here are a few of things to look out for as a regulatory writer to avoid being accused of it:

1. Do not copy-paste content from scientific articles; always approach articles in a critical way
2. Always cite your sources properly, providing access to full-text original articles
3. Always keep in mind that a regulatory writer is not submitting the data; he/she is critically appraising them. A regulatory writer is like a post-publication peer-reviewer!



Overall

EU-MDR requirements for identification of reliable sources of evidence, as well as for the critical appraisal and interpretation of both favourable and unfavourable data related to the safety and performance of a medical device, are incompatible with the definition and manifestations of plagiarism.

Consequently, as long as proper and full citation practices are implemented, a CER regulatory writer cannot be accused of plagiarism and is in fact acting as a safety net protecting the authorities and the notified bodies from falsified, fabricated and/or manipulated clinical data. Inclusion of exact words properly cited, when needed, allows to immunize the regulatory evaluation process against understated or distorted clinical results; thus, it may prevent regulatory scandals and exposure of the general population to risk13, 14.

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