Clinical trial transparency and disclosure from the medical writing perspective

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It's been more than six years since our last *Medical Writing* edition dedicated to clinical trial transparency and disclosure.[1] Since then, we have seen the full implementation of the long-awaited EU Clinical Trials Regulation (CTR)[2], the pause and restart of EMA Policy 0070[3], and of course a global pandemic which resulted in a worldwide surge in freedom of information requests for Covid-19 vaccine clinical trial data. Although many of the regulations and policies governing public disclosure of clinical trial data and documents remain unchanged, we have seen significant changes in the way these are implemented. As those of us who work in this field know all too well, the landscape is ever changing, and it is essential to keep up to date with those changes. Resources such as the Drug Information Association Clinical Trial Disclosure Community,[4] PHUSE Data Transparency Working Group,[5] and Clarity and Openness in Reporting-E3 based (CORE) Reference[6] provide invaluable updates and insights. This issue of *Medical Writing* touches on a number of different aspects of clinical trial transparency and disclosure, all of which involve medical writers as key stakeholders

Following a public consultation on the rules for the operation of the EU CTR and its Clinical Trials Information System (CTIS), the EMA Management Board adopted revised CTIS transparency rules[7] in October 2023. In this issue **Merete Jørgensen, Kathy Thomas, Matthias Zerm,** and **Robert Paarlberg** describe the impact of these revised rules on the protection of personal data and commercially confidential information within CTIS and the key role medical writers play in preparing disclosure-ready clinical documents. They also discuss interrelated requirements of other regulations applicable for public disclosure of clinical trial information within the EU/EEA.

Following the application of the EU CTR with the go-live of CTIS on January 31, 2022, a three-year transition period started where clinical trials originally authorised under the Clinical Trials Directive 2001/20/EC[8] and are expected to continue in the EU/EEA after January 2025 must meet the requirements of the EU CTR. In their article on transitioning trials from EudraCT to CTIS, **Mirjana Miric** and **Sarah Bly** describe this process. They highlight the very short turn-around times for addressing requests for information and how medical writers play a critical role in meeting

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these deadlines if clinical documents need updating. Mirjana and Sarah also stress that the work is not done once transition is completed as there is a substantial amount of work required in preparation of the first substantial modification, especially if a minimum dossier was submitted for transition.

Pooja Phogat and **Stuart Donald** provide an excellent summary of the different clinical trial transparency requirements, highlighting how medical writers can take a lead in ensuring these are met while maintaining data privacy, confidentiality, and the integrity of data. Their article also underlines the increasing complexity of clinical trial transparency by highlighting the regional differences in transparency requirements which present challenges for global studies.

Although only recently mandatory with the application of the EU CTR in January 2022, many clinical trial sponsors have long recognised the value in producing summaries of clinical trial results in lay language. In her article on plain language summaries of clinical trial results, **Lisa Chamberlain James** explores the significance of these highly specialised documents. She describes the importance of involving patients in the development of these results summaries and discusses how artificial intelligence provides the opportunity to streamline the process – but emphasises that medical writers still play a crucial role in ensuring quality results.

As already mentioned, CORE reference provides invaluable guidance on best practice in the preparation of clinical study reports with disclosure and transparency in mind. **Zuo Yen Lee, Alison McIntosh, Vivien Fagan**, and **Sam Hamilton** present the findings of the 2023 CORE Reference Utility Survey aimed at measuring awareness and perceived usefulness of these resources by the regulatory medical writing community. They compare results of this survey with the previous survey in 2017 and report an increased use of the CORE Reference open-access manual and confirm that the manual remains a useful tool when preparing disclosure-ready clinical study reports (CSRs). Positive responses were also received on the usefulness of the bi-monthly "News Summaries" to provide subscribers with updates on major changes in regulatory reporting and public disclosure requirements from around the world, including Asia.

The Covid-19 pandemic perfectly demonstrated the importance of accessible and understandable information being made available to the public in a timely manner to empower patients and foster trust. **Devaki Thavarajah, Sylvia Baedorf Kassis, Alyssa Panton, Barbara Bierer**, and **Trishna Bharadia** describes PHUSE and MRCT Centre's experiences creating an informational video series and complementary infographics aimed at explaining clinical trials to patients and the general public, focusing on how data are collected, used, shared and protected.

In addition to the EU CTR requirement for plain language summaries of clinical trial results, some journals also now publish plain language summaries alongside scientific publications. In their article **Slávka Barónková, Adeline Rosenberg, Christopher Winchester,**

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Valérie Philippon, **Jo Gordon**, and **Joana Osório** report on findings from a survey conducted in 2022/23 by the multi-sponsor collaboration Open Pharma. The survey indicate journals are not routinely supporting submission of a plain language summary, and where they do there is significant variability in the content, format, and accessibility.

As well as the "Clinical Trial Transparency and Disclosure" edition feature articles, we also have the regular "Regulatory Public Disclosure" section supplied by **Sam Hamilton** and the **CORE Reference Team**. The team present a selection of key regulatory information to support the continuing professional development needs of medical and regulatory writers, including links to information related to the EMA CTIS re-launch on June 18, 2024, and the accompanying EMA Guidance document describing how to approach the protection of personal data and commercially confidential information while using CTIS. Alongside this, they have prepared a handy, "bitesize" comparison between Policy 0070 and EU CTR.

Regulatory medical writers have an important role to play in the process of preparing clinical documents suitable for public disclosure, and separately can have a role in preparing clinical trial datasets suitable for data sharing. The methods used to manage the risk of de-identification of individuals in both processes have commonality. In the regular "In the Bookstore" section **Alison McIntosh** reviews *Guide to the De-Identification of Personal Health Information* and advises that this book provides useful background to the topic alongside details of the statistical concepts applied to de-identify clinical datasets.

We will continue our exploration of different aspects of clinical trial transparency and disclosure by publishing two further articles in the December issue of MEW, and both should not be missed.

One will address the need for different transparency requirements globally and how this presents challenges in maintaining consistency with publicly disclosed information, particularly for multi-national trials. **Maren Anne Moehlmann**, **Zhen (Sophie) Yu**, **Yu (Julia) Zhou**, and **Qiang (Johnson) Liu** will give a detailed insight on the processes a global pharmaceutical company uses to manage and harmonise global and local clinical trial registration and results disclosure. They will describe how they operationalise "central disclosures" in Germany, EU, and US versus "local disclosures" using the example of China. Be sure to keep an eye out for this important article in the next edition of MEW.

The other will examine the growing complexity of disclosure and transparency by highlighting the need to balance the requirements of regulations aimed at ensuring transparency of clinical trials with those governing the protection of personal data. **Bina Mehta**, **Sayanti Sau**, **Dhruv Patel**, and **Akanksha Rai** will look at transparency requirements from a data protection and privacy perspective. Their article will raise the crucial topic of GDPR[9] and the importance of understanding the roles of Data Controller and Data Processor, and the need for Data Processing Agreements. They will describe their experiences supporting both EMA Policy 0070 and CTIS submissions, highlighting keys to success, the impact of medical writers, and lessons learned. Please look out for this interesting article in the December edition of MEW.

The guest editors would like to thank all authors for their valuable contributions and for openly sharing their knowledge and expertise on clinical trial transparency and disclosure. We would also like to thank the MEW editorial team for their help and support in producing this issue. Finally, we hope you find this themed issue of *Medical Writing* interesting as well as informative and beneficial.

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