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EMA Adopts Revised CTIS Transparency Rules

November 2, 2023

On 5 October 2023, the European Medicines Agency (EMA) adopted revised transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System (CTIS). The CTIS plays a fundamental role in facilitating the exchange of clinical trial information within the European Union (EU), as provided in the Clinical Trials Regulation (CTR).

The previous iteration of the CTIS transparency rules requires publication of the almost complete clinical trial application dossier, except for personal data and commercially confidential information (CCI). The rules also permit sponsors to request the deferral of publication of certain clinical trial documents.

To ensure easier access to pertinent clinical trial information, the revised CTIS transparency rules will introduce a more user-friendly CTIS public website. Changes are intended to simplify access to information for clinical trial stakeholders, increase awareness of possible treatment options, rationalise the amount of clinical trial data that needs to be published and eliminate deferrals, resulting in earlier access to important documents.

The revised CTIS transparency rules are expected to apply in the second quarter of 2024, once their technical implementation in the CTIS has been finalised.

Removal of the deferral mechanism

One of the key rule changes is the removal of the deferral mechanism which permits sponsors of clinical trials to delay publication of certain clinical trial documents for up to seven years after the end of the clinical trial to protect CCI. The maximum deferral period depends on the categorization of the clinical trial and the type of document for which deferral is requested. Many sponsors have been relying on this deferral mechanism while limiting redactions of CCI. However, balancing the deferral mechanism and redaction has been challenging for sponsors and has created uncertainties in relation to the submission of documents to CTIS and requests for deferral.

Removal of the deferral mechanism contributes to simplifying the publication rules and reducing the potential risk that CCI may be published once the deferral period ends. However, this also means that sponsors will become more reliant on redaction to protect CCI in clinical trial documentation.

The deferral mechanism and related functionalities in CTIS will remain in place until a new CTIS public website – implemented in line with the revised CTIS transparency rules – is available.

Revised publication rules for structured data fields in CTIS

Structured data fields, which are the fields populated by users in CTIS, include information concerning the trial title, study design, inclusion/exclusion criteria to take part in the trial, primary and secondary endpoints, details on investigational medicinal products used in the trial, clinical investigator sites and sponsor contact details. These fields also include data relating to the authorization status of a clinical trial and key dates, such as the start of the clinical trial, recruitment of patients or the end of the clinical trial.

These fields capture essential trial details but cannot be redacted. The EMA, therefore, emphasises the importance of ensuring that personal data and CCI is excluded from structured data fields.

Details regarding the content of the structured data fields, and the related timing of publication on CTIS, are established in Annex I to the revised CTIS transparency rules.

Revised publication rules for documents submitted in CTIS

In accordance with the previous iteration of the CTIS transparency rules, almost all data and clinical trial documents submitted as part of the clinical trial application are published at the earliest opportunity. Exceptions to this principle apply if the sponsor of the clinical trial requests deferral of publication at the time of submitting a clinical trial application. In addition, documents to be published may be redacted to protect CCI and personal data. Accordingly, the CTIS offers the possibility to prepare and submit two versions when submitting documents in CTIS:

- A version 'for publication' for redacted documents.
- A version 'not for publication' that may contain personal data and CCI as necessary for scientific and regulatory review carried out by EU Member States.

The revised publication rules maintain the submission of two versions of documents uploaded to CTIS. However, the type of documents and timing of disclosure have been amended. In particular, the revised transparency rules aim to focus the publication of documents on those that are more impactful for patients and clinical researchers. As a result, the number of documents to be publicly disclosed has been limited.

Details regarding the clinical trial documents that will be publicly disclosed, and the related timing of their publication in CTIS, are established in Annex I to the revised transparency rules.

Conclusion

The previous iteration of the CTIS transparency rules led sponsors of clinical trials to balance redaction of CCI with the deferral mechanism to protect CCI. However, these rules date back to 2015. As a result, the EMA announced, following entry into application of the CTR in 2022, that a public consultation would be held to consider experience with use of the system. The public consultation was open for comments between May and June 2023 and revealed that implementation of the new CTIS system – combined with the CTIS transparency rules – has proven to be complex in practice.

The revised CTIS transparency rules aim to streamline access to critical clinical trial information by focusing on publication of structured data fields and key documents. The rules also remove the deferral mechanism and aim to simplify implementation of transparency requirements while permitting sponsors to protect personal data and CCI.

However, many sponsors have relied on the deferral mechanism to delay publication of clinical trial documents with minimal redactions of CCI. As a result, sponsors may need to revise their internal procedures for managing CCI and fulfilling their transparency obligations under the CTR. Sponsors also should ensure that all personnel involved in the submission of clinical trial applications are appropriately trained on the requirements of the new CTIS transparency rules ahead of entry into application of these rules in 2024.

Cooley legal trainee Alix Vermulst also contributed to this alert.

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