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European Medicines Agency Publishes Q&A on Clinical Trial Data Transparency

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Following the entry into application of the Clinical Trials Regulation (EU) 536/2014 (CTR) for all initial clinical trial applications on 31 January 2023, the European Medicines Agency (EMA) has published a Q&A document concerning the transparency obligations established in the CTR in relation to information submitted in support of an application. The Q&A provides responses to questions raised by clinical trial sponsors in the context of a survey developed by the European Commission, the EMA and the Heads of Medicines Agencies. The survey sought to identify the challenges relating to the implementation of the CTR and assess the degree to which sponsors understand the obligations foreseen therein, including disclosure rules.

One of the challenges identified in the survey was compliance by applicants with transparency requirements in the Clinical Trials Information System (CTIS), the single electronic entry point through which the submission, assessment and reporting of clinical trial information is conducted for all initial clinical trial applications submitted on or after 31 January 2023. The two main concerns articulated by sponsors in relation to disclosure obligations are deferrals of publication of trial data and redaction of trial documents to protect commercially confidential information (CCI).

Deferral of publication of documents

The Q&A provides guidance regarding deferral of publication of clinical trial information. Although, in principle, clinical trial sponsors must publish clinical trial documents and data immediately upon submission, a deferral mechanism is available. This mechanism provides sponsors with the possibility of seeking approval to delay the publication of certain clinical trial data, such as the clinical trial protocol or the investigator's brochure, for a specified period of time. EU member states also may choose to delay the publication of the questions included in their assessment reports and the evaluation of the related responses provided by the sponsor. The purpose of this delay is to protect CCI and personal data. The duration and scope of the deferral period varies, depending on the category under which a clinical trial falls. As an exception, for trials conducted in situations of public health emergency, deferrals are not accepted.

According to the Q&A, where requests for deferrals are made, the reporting member state (RMS) or the member state concerned (MSC) must specifically reference the category in which the individual trial falls. This is important, as any related deferral timeline will be determined based on this categorization. Member states may also comment on the deferral timeline proposed by the sponsor. If the request for deferral is accepted, the same deferral timeline will apply to the publication of assessment reports or requests for information (RFIs) by the MSC. The Q&A also provides that the type of justification sponsors should provide in support of their request for deferral is information relating to the applicable trial category.

In addition, the Q&A clarifies that there is no procedure in place to inform sponsors about the status of their request for deferral. Instead, an absence of related RFIs from the national competent authorities or sufficient response to RFIs will signal that a deferral request has been accepted.

Redactions in relation to CCI and personal data

The Q&A provides that, although not mandatory, RMS and MSC may review and comment on the extent of redactions proposed by sponsors in the clinical trial documents included in the CTIS submission. The purpose of this review is to ensure that transparency rules are respected by sponsors. The Q&A adds that, as a general rule, extensive redaction will be considered to defeat the CTR's aim of achieving a high level of transparency of trial data. This means that the same documents or data should not be subject to both redaction and deferral requests, except in limited circumstances where both measures are necessary to protect CCI.

In terms of practical advice in relation to redactions, the Q&A suggests that CCI be included in the 'not for publication' section of trial applications by placing it in a red box. This will help reviewers understand which parts of the trial applications are considered CCI that should not be incorporated into publicly available assessment reports or RFIs.

Most documents requiring signatures and those that include personal data must be uploaded under the 'not for publication' section of the application in the CTIS, unless such information is redacted. The name and surname of the principal investigator and the person issuing a site suitability document are, however, excluded from this rule and will be published in the CTIS, as foreseen in the **Appendix on disclosure rules to the 'Functional specifications for the EU portal and EU database to be audited'**.

Next steps

The Q&A is expected to be updated as soon as more information becomes available and will form part of the draft **Guidance document on the protection of personal data and CCI in documents uploaded and published in the CTIS**.

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