Client Alert

April 2022

EU: Increased transparency under the Clinical Trials Regulation — sponsors should take action to protect commercially confidential information

In brief

The new Clinical Trials Regulation (**CTR**) became applicable on 31 January 2022, following achievement of the full functionality by the new Clinical Trials Information System (**CTIS**), bringing more transparency into the area of clinical trials.

CTIS is a publicly accessible system that contains the data submitted in accordance with the CTR. The CTIS was set up to streamline the flow of information between the EU member states, the sponsors and the EU members states and to enable access of the EU citizens to information on medicinal products. It is operated by the European Medicines Agency.

In principle, the information in the CTIS is public. However, to protect the legitimate economic interest of sponsors, the CTR provides for a carve-out to protect sponsors' commercially confidential information. Sponsors will be able to rely on this carve-out as discussed in more detail below. Sponsors are advised to review the draft Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the CTIS that is currently under the public consultation and submit their comments by 8 September 2022.

In this issue

No publication before the decision on approval of a trial

The approach to publication of data and information in the CTIS will differ depending on whether or not the decision on approval of a clinical trial in question has been issued.

During the process for approval of a clinical trial, the information submitted by sponsors as part of the clinical trial application and any exchanges with regulators are in principle considered confidential and will not be published (unless in the exceptional case where an overriding public interest is established as discussed below).

After a decision, of any kind (authorized, authorized with conditions, or not authorized) has been issued by the concerned member states on the clinical trial application, the data and documents submitted to CTIS for the trial, including exchanges with regulators, will be made available to the public, unless the sponsor has applied for a deferral, which is granted.

Deferral of commercially confidential information

When populating the data fields of the CTIS at the time of submission of an initial application, the sponsor will be able to request a deferral. If the member states concerned grant a deferral during the evaluation of the application, publication of a set of data and documents (e.g. protocol, investigator brochure, informed consent information sheet) will be delayed.

EMA has published detailed guidance on how the deferral rules will apply in the Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 and Appendix thereto (**Specifications**). EMA has also opened public consultation of the draft Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS) (**Draft Guidance**).

Based on the Specifications, the information on clinical trials will be released gradually taking account of the marketing authorization status of a product and of overriding public interest in disclosure. For this purpose, the clinical trials are divided into three categories. The timing of publication of data and documents are adjusted according to whether the clinical trial falls into one of the below categories:

1. Category 1 clinical trials (e.g., phase I clinical trials, bioequivalence and bioavailability trials of innovative products, new generic products and biosimilar product)
2. Category 2 clinical trials (phase II and phase III clinical trials)
3. Category 3 clinical trials (phase IV trials and low-intervention trials)

The sponsor will be able to choose a trial category. In case a trial has more than one phase, the maximum publication deferral will be the one indicated in the highest associated category.

For each type of data/document the timing and conditions for disclosure are specified in a tabular format contained in an Appendix. The timing is based on key milestones of the clinical trial identified in the CTR – decision on the trial, end of the trial, up to 12 months after the end of the trial and one additional milestone defined in the Appendix to simplify and standardize release of data and documents, which is set up to a maximum of 7 years after the end of the trial for category 1 trials and up to a maximum of 5 years after the end of the trial for category 2 trials. For example, for the clinical trial protocol, the deferral period may be up to 7 years for category 1 trials and up to 5 years for category 2 trials. For category 3 trials, the protocol is not normally considered to be commercially confidential and the public interest is of overriding importance as the investigational products are in routine use in medical practice. However, the sponsor may request deferral to protect commercially confidential information up to the time when the summary of results is made public, i.e. for up to 12 months after the end of the trial.

Based on the Draft Guidance, during the evaluation phase, the concerned member states, in collaboration with and via the reference member state, will assess whether the trial category chosen by the sponsor is correct depending on the trial phase and the clinical development status of the medicinal product(s) being tested and can require the sponsor to modify the chosen trial category or the proposed deferral timing.

The deferral will only be granted if it is agreed by all concerned member states.

Redaction of commercially confidential information

In addition to the deferral mechanism, CTIS allows sponsors to redact commercially confidential information. Regardless if deferrals are requested by the sponsor and endorsed by the reference/concerned member state(s), the sponsor has the obligation to submit a document version 'for publication' (that should not contain personal data and commercially confidential information) and a version 'not for publication' (that will contain all information required for assessing the application, and may contain commercially confidential information) based on the content of the document and as long as the protection of commercially confidential information and personal data is necessary. Once the deferral period elapses, for the applicable documents based on the trial category, the version of the documents 'for publication' uploaded in the CTIS secure domain will be published.

Data that will always be published

Sponsor will not be able to defer publication of/redact certain trial-related data. Specifically, the following data will be made public for all clinical trials registered in the CTIS:

- the main characteristics of the trial comprising design, scientific and, where applicable, therapeutic intent, title, identification of the investigational medicinal products (IMPs), treatment arms, treatment population and number of subjects, inclusion and exclusion criteria and main objectives and endpoints;
- conclusion of the assessment and decision on the trial;
- information updated during the trial to indicate the start and end dates of recruitment;
- substantial modifications to the trial;
- the end date of the trial, with reasons for which trials are ended prematurely where applicable, and, 12 months later, the summary of results and a summary in lay language;
- clinical study reports for clinical trials on medicines for which a marketing authorisation has been granted, the procedure completed or the marketing authorisation application withdrawn.

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Overriding public interest in disclosure

The overriding public interest in disclosure may prevail in exceptional circumstances, for example, where there are very serious safety incidents. The decision to invoke such overriding public interest in disclosure is made by the concerned member states, supported by the EMA and the EU Commission.

Recommendations

The increased transparency under the CTR may result in the premature publication of sensitive information related to clinical trials, unless sponsors take actions. Sponsors are recommended to develop strategies ensuring that the information and documents submitted through the CTIS are timely reviewed and assessed by qualified experts to identify the documents and information that contain commercially confidential information and, where possible, request deferral / redact commercially confidential information at the time of submitting the initial application for a clinical trial. In addition, sponsors are recommended to undergo the workshops and trainings on CTIS functionality carried out by EMA and available on EMA's website.

Finally, the public consultation concerning the Draft Guidance is open until 8 September 2022. The sponsors may provide the comments to the Draft Guidance using the template form and the address available on EMA's website.

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