European Commission Updates Q&A on EU Clinical Trials Regulation

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On 13 April 2022, the European Commission published an updated version of its Q&A on the EU Clinical Trials Regulation (*i.e.*, Regulation (EU) No 536/2014 of 16 April 2014; the ***CTR***) (*see*, attached copy).

The updated Q&A forms part of Volume 10 ("Clinical trials guidelines") of EudraLex and includes the following changes:

- an updated answer to question 1.4: What document/data shall be submitted with an application?
- an updated answer to question 1.5: How to proceed in case of discrepancies between the CTR and ICH Good clinical practice guidance?
- an answer to new question 1.22: What are the legal warranties for the validity of decisions by tacit approval?
- an answer to new question 1.23: Appeal and implementation of change of decision due to an appeal
- an updated answer to question 5.8: What should be included in the protocol synopsis described in Annex I, D.24?
- an answer to new question 6.5: What is the recommended strategy for the publication of trial documents with proprietary information?
- an updated answer to question 11.10: What are the consequences of switching the regulatory framework applicable to a clinical trial?
- an updated decision tree in Annex I to the Q&A to establish whether a study is a "clinical trial".

The CTR repealed and replaced the Clinical Trials Directive (*i.e.*, Directive 2001/20/EC; the ***CTD***) as from 31 January 2022. However, the CTD will continue to apply until 31 January 2025 to (i) clinical trial applications submitted before 31 January 2022; and (ii) clinical trial applications submitted between 31 January 2022 and 31 January 2023 in which the sponsor opts for the CTD system (*see*, Van Bael & Bellis Life Sciences News and Insights of 9 August 2021).

Ensuring a greater level of harmonisation of the rules for conducting clinical trials throughout the EU, the CTR introduces an authorisation procedure based on a single submission and an assessment procedure leading to a single decision. At the heart of the CTR system is the Clinical Trial Information System (***CTIS***). Comprising an EU Portal and EU Database, CTIS ensures a single-entry point for the submission of data and information relating to clinical trials by sponsors, evaluation and supervision by Member State health authorities, and access to data and information relating to clinical trials by the public (*see*, Van Bael & Bellis Life Sciences News and Insights of 11 October 2021).

Attachments:

Updated Q&A

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