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European Commission Publishes Updated Q&A on Clinical Trials Regulation

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In December 2022, the European Commission published an updated version of the Q&A guidance on the Clinical Trials Regulation (CTR). This new version was issued ahead of the 31 January 2023 deadline from which all new applications for the approval of clinical trials must be submitted in accordance with the CTR.

The most important amendment to the Q&A is the inclusion of a new Annex III.

The application dossier for the approval of a clinical trial in accordance with the CTR is composed of two parts. Part I of the application dossier relates to scientific aspects of clinical trials that are considered to be scientifically harmonized among European Economic Area (EEA) countries. Part II relates to country-specific, patient-level requirements, which may vary from one EEA country to another. The European Commission has developed standardized templates for documentation required for Part II of the application dossier, but some EEA countries have developed their own national templates.

As a result, when operating in the EEA, sponsors may be confronted with divergent national requirements of individual EEA countries. The updated Q&A aims to provide a consolidated list of national sources where sponsors can identify national requirements and any applicable templates in those countries. This information should assist sponsors in navigating the specific requirements of individual EEA countries, as well as submitting high-quality and appropriate documents as part of their application dossiers for the approval of clinical trials.

Annex III provides a table listing the websites of all EEA countries, where sponsors can find information regarding national requirements of each EEA country. It also lists the email addresses for those countries' national competent authorities to which sponsors may submit inquiries.

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