PINK SHEET
CITELINE REGULATORY

05 Jan 2023 | **News**

Updated EU Guide Helps Sponsors Steer Through National Clinical Trial Requirements

by Vibha Sharma

The EU guideline on the Clinical Trials Regulation has been updated with a list of member state websites where sponsors can find information on national requirements for trial applications.

The European Commission has issued *updated guidance* on the Clinical Trials Regulation to help trial sponsors navigate the complex maze of EU member state-specific requirements when preparing their study dossiers.

The commission's Q&A guide on the CTR was last month updated with, among other things, a new Annex III containing a list of member state websites where sponsors can find "important information to submit high quality" documents on national requirements as part of their clinical trial applications.

The annex was one of the most eagerly awaited aspects of the CTR Q&A guide. It has been published just weeks before the 31 January deadline when compliance with CTR provisions becomes mandatory for all new trials.

The CTR requires sponsors to submit a two-part trial dossier – a harmonized, pan-EU part I (on scientific and medicinal product requirements) and part II (on national and patient-level requirements).

While the commission has developed standardized templates relating to Part II of the trial dossier (eg, on informed consent and recruitment procedures, compensation for trial participants), member states are not obliged to accept these harmonized templates. (Also see "*Centralized Templates To Help Harmonize Trial Dossiers Requirements Across The EU*" - Pink Sheet, 23 Sep, 2022.)

© Citeline 2024. All rights reserved.

In fact, several member states have developed their own Part II templates in accordance with national requirements and sponsors have been struggling with compliance on this front when preparing study dossiers.

Last year, the sponsor one of first the studies that was voluntarily submitted for approval under the CTR complained about the "endless" list of different and sometimes inconsistent national requirements they faced with respect to their study. (Also see "*Not A Smooth Ride: How One Of The First Studies Navigated The EU Clinical Trial Portal*" - Pink Sheet, 3 Aug, 2022.)

The commission was initially planning to update its Q&A guideline with information in Annex III on the acceptability of the standardized Part II templates by each member state. The scope of the annex is somewhat changed in that it lists in one place all national websites where information on member state-specific Part II requirements and related templates can be found. It also contains a list of email addresses for each member state to support further enquiries by sponsors in relation to Part I or Part II documents.

The commission stressed that it could not be held responsible for the quality and completeness of the information reported in Annex III or for the functioning of the national websites. It said the information in the annex was based on the feedback it had received between 10 November and 22 December 2022 from the designated CTR national contact points appointed by each member state.

The updated guideline is the latest attempt by the commission to help ensure harmonized requirements for approving trials under the CTR. To this end, it had earlier made several changes to the Q&A guideline to ensure that member state-specific requirements, where imposed, have a clear legal basis and had urged sponsors to push back on requirements where this is not the case. (Also see "*Sponsors Urged To 'Push Back' On EU Country-Specific Clinical Trial Requirements*" - Pink Sheet, 14 Jul, 2022.)

The latest update also provides clarity on other issues, including:

- Transitioning existing mono- and multi-national trials (approved under the erstwhile Clinical Trials Directive) to the CTR.
- Complying with the principles of Good Laboratory Practice to support trial authorization under the CTR.
- Supplying patient-facing documents to trial participants in a language they can understand.
- The assessment of "multi-trial substantial modification" – ie, where a substantial

© Citeline 2024. All rights reserved.

modification is related to a document common to various clinical trials of the same sponsor and the same investigational medicinal product.

© Citeline 2024. All rights reserved.