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European Medicines Agency

Message to sponsors transitioning trials to CTR/CTIS

Clinical trials (CTs) authorised under the Clinical Trials Directive (CTD) likely to be ongoing beyond 30 January 2025 need to be transitioned to the Clinical Trials Regulation (CTR). Details of the requirements for transitioning CTs are provided in the European Commission's Guidance for the transition of clinical trials.

The transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation (CTR) is open to sponsors until the end of the 3-year transitional period, on 30 January 2025, without the need to discontinue a clinical trial or put a trial on hold.

Sponsors should, however, take into account the time necessary for completion of the authorisation procedure under Chapter 2 of the CTR and the European Commission's guidance. Therefore, **sponsors are strongly advised to submit their applications prior to 30 January 2025 taking into account the assessment time**, which can extend from 1 week (expedited process) to up to 106 days in case a full trial application is needed.

By late October 2023, only around 390 transitional trials have been submitted to CTIS out of an estimated 4,000 - 6,000 trials pending to be transitioned by 30 January 2025.

Further resources and guidance from the European Medicines Regulatory Network are available on the CTIS website (under the section "Transitioning Trials") in order to support sponsors transitioning their trials to the CTR/CTIS.

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