



End of submissions for initial CTR pilot files on 14 October 2021

date: 05/08/2021

The pilot project for the new Clinical Trial Regulation (CTR) will end when the CTR Regulation enters into force. All initial dossiers under the CTR pilot procedure must be submitted by 14 October 2021.

The [pilot project for the new Clinical Trials Regulation \(CTR\)](#) is limited in time and will end when the CTR Regulation enters into force, as foreseen in the [guidance for sponsors](#).

The submission of initial clinical trials under the CTR pilot procedure will still be possible until Thursday 14 October 2021. This allows all initial dossiers to be closed before the regulation comes into force on 31 January 2022.

The date of 14 October 2021 is the last available time slot that can be reserved for the submission of an initial CTR pilot dossier. However, in accordance with the [Q&A on time slots](#), this last dossier can be submitted between Monday 11 October and Sunday 24 October 2021.

The reservation system with time slots is therefore maintained until 14 October 2021, with the same volume of dossiers accepted per week: two dossiers, with one time slot available on Tuesday and another on Thursday.

Substantial changes following the pilot procedure will continue to be accepted until the end of the trial or until the transition from the trial to the regulation (which must be made no later than three years after implementation of the CTR).

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