ACT EU

Accelerating Clinical Trials in the EU

NEWS ARTICLE | 22 April 2024 | European Medicines Agency | 1 min read

Launch of revised CTIS transparency rules

The revised transparency rules *(https://www.ema.europa.eu/en/documents/other/revised-ctis-transparency-rules_en.pdf)* for the Clinical Trials Information System (CTIS) will become applicable on 18 June 2024, with the launch of a new version of the CTIS public portal *(https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en)*.

The updated rules strike a balance between transparency of information and protection of Commercially Confidential Information (CCI). They benefit patients, because key clinical trial information, that patients flagged as being most relevant for them, is published early. They also introduce process simplifications that benefit clinical trial sponsors who have to protect commercially confidential information and personal data.

One of the key changes under the updated rules is the removal of the deferral mechanism, which previously allowed sponsors to delay the publication of certain data and documents for up to seven years after the end of the trial to protect commercially confidential information.

The new version of the CTIS public portal *(https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en)* will display data and documents on clinical trial applications submitted on or after 18 June 2024, in line with the timelines defined in the revised transparency rules. Moreover, the total number of trials that are publicly available will increase substantially. Clinical trials submitted to CTIS prior to the application of the revised transparency rules will also be publicly available, in line with the ACT EU_Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS *(https://accelerating-clinical-trials.europa.eu/system/files/2023-11/ACT%20EU_Q%26A%20on%20protection%20of%20Commercially%20Confidential%20Information%20and%20Personal%20Data%20while%20us*

In the interim period until 18 June 2024, sponsors may already follow the principles of the revised CTIS transparency rules, as defined in section 4 of the ACT EU Q&A *(https://accelerating-clinical-trials.europa.eu/system/files/2023-11/ACT%20EU_Q%26A%20on%20protection%20of%20Commercially%20Confidential%20Information%20and%20Personal%20Data%20while%20us*

Useful material for sponsors

- For an overview of what will be published when, including details on the disclosure of information on trials submitted prior to the application of the new rules expected on 18 June, please refer to the quick guide for users *(https://accelerating-clinical-*

trials.europa.eu/document/download/a101771b-0be7-492f-b8bd-7f551ffbb7a7_en?filename=Revised%20CTIS%20transparency%20rules%2C%20Interim%20period%20%26%20Historical%20trials_quick%20guide%20for%20

- The CTIS Bitesize talk on the transparency rules (https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-training-materials-ctis-pre-requisites-and-updates-transparency-rules) provides an overview of the changes in CTIS.
- A follow-up CTIS Bitesize talk on the topic is planned on 20 June 2024 (https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-bitesize-talk-revised-transparency-rules-new-ctis-public-portal), to further support sponsors in adapting their business processes.

The Guidance and Q&As section (https://euclinicaltrials.eu/guidance-and-q-as/#qas-transparency) of the CTIS website as well as the ACT EU webpage on Implementation of the Clinical Trials Regulation (https://accelerating-clinical-trials.europa.eu/our-work/implementation-clinical-trials-regulation_en) include all resources and support materials on transparency in CTIS.

Details

Publication date	22 April 2024
Author	European Medicines Agency

Joint initiative by