2 July 2026
European Medicines Agency

Joint response from European Medicines Regulatory Network to letter from Health Action International and other health groups on missing clinical trial results in CTIS

Dear Mr Vidal,

Thank you for writing to EMA's Management Board on 15 June 2026 to share your policy brief and suggestions for improving sponsors' compliance with Article 37 of the Clinical Trials Regulation 536/2014 (CTR).

The CTR, which entered into application in 2022, represents an important move towards increased transparency and better access to information relating to clinical trials. Under Article 37 of the CTR, sponsors are legally required to submit a summary of trial results, accompanied by a layperson summary, to CTIS within the applicable timelines following the end of a trial.

We welcome your ongoing support and suggestions for further actions to increase the number of completed trials for which results are to be made publicly available.

Monitoring compliance with results submission (both scientific and layperson summaries) and ensuring adequate quality of the content is a shared responsibility between EU/EEA Member States, the European Commission and EMA. The Member States are responsible for authorising and supervising clinical trials in their territory, the Commission is responsible for ensuring adequate implementation of the CTR and EMA is responsible for developing and maintaining the CTIS functionalities that enable sponsors to meet their legal obligations.

Transparency of clinical trial information is a key priority for the European Medicines Regulatory Network. As such, the Network continues to actively drive measures to further improve transparency, for example through the revision of the CTIS transparency rules in June 2024 which ensured timely access to clinical trial data.

To further increase and monitor compliance with the publication requirements, the following actions are also being undertaken, some of which address a number of your proposals:

- CTIS provides sponsors with notices and alerts within the system, including regular reminders of their obligation to submit the results and layperson summaries. This functionality has been recently supplemented with direct email notifications sent to CTIS users;
- enhanced monitoring capabilities have been developed to allow the European network to track the timely submission and publication of trial results per Member State;
- training materials for sponsors have been revised with improved guidance and detailed instructions in the sponsor handbook on how to submit trials results (see chapter 5 of the handbook);
- regular reminders of transparency obligations are sent through established communication channels such as the national contact points via the Commission's Expert Group CTAG (Clinical Trials Advisory Group), the ACT EU Multi-stakeholder Platform Advisory Group, as well as the Clinical Trials Highlights newsletter;

- by the end of 2026, the quarterly reports on the performance of the EU clinical trials environment will include the number of trials with available summaries of results (these reports are published on the ACT EU website);
- Member States are also considering further measures to be implemented at national level to improve compliance with the sponsors' legal obligations.

In addition, the Network is committed to making clinical trial results in CTIS accessible and understandable, enabling the public to benefit from transparent and reliable information on EU clinical trials. For example, the Clinical Trials Map launched in March 2025 is designed to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials conducted in their area, increasing access to clinical research in the EU.

The recently published ACT EU 2026-2027 workplan also includes a communication campaign targeting clinical trial sponsors. The campaign emphasises the importance of submitting high-quality data to CTIS, with a particular focus on the timely submission of results summaries. Actions under consideration as part of the campaign include measures previously used to successfully increase the posting of results in EudraCT.

Lastly, while we acknowledge the importance of prompt submission of the summary results within the defined timelines, we would like to highlight that the Network has taken additional transparency measures through the publication of clinical data submitted as part of marketing authorisation applications on both EMA's website and the CTIS public website. This is intended to help researchers reassess clinical data, avoid duplication of clinical trials and build public confidence in EMA's scientific and decision-making processes.

EMA, the European Commission and the Heads of Medicines Agencies (HMA) will closely monitor the impact of these measures and will continue to review the need for further action to ensure the timely publication of clinical trial results.

We thank you for bringing this topic to our attention on behalf of Health Action International and supporting organisations. Your letter and policy brief has been discussed by the ACT-EU Steering Group and will be shared with EMA's Management Board for their awareness.

We look forward to continuing our close work in the interest of European patients and the public and will keep you informed of the outcomes of our discussions.

Yours sincerely,

Signature on file

Rui Santos Ivo

EMA Management Board Chair

On behalf of the European Medicines Regulatory Network