To: Mr Rui Santos Ivo, Chair, EMA Management Board

Cc:

Ms Emer Cooke, EMA Executive Director

Mr Marco Marsella, DG SANTE.DDG1, European Commission

Ms Olga Solomon, DG SANTE.D.1, European Commission

Ms Agnes Mathieu Mendes (Chair of the ACT-EU Steering Group), DG SANTE.D.2, European Commission

Dr María Jesús Lamas Díaz (Chair of the HMA Management Group), AEMPS

Please respond to: Jaume Vidal, Health Action International, jaume@haiweb.org

Amsterdam, 15 June 2026

Dear Mr Santos Ivo,

We urge you to raise the issue of weak sponsor compliance with legal clinical trial results reporting requirements on the Clinical Trials Information System (CTIS) with the EMA Executive Director and the Chair of the HMA Management Group, and to place the issue onto the agenda of the October 2026 meeting of EMA's Management Board.

The Clinical Trials Regulation requires sponsors of Phase II-IV drug trials conducted in Europe to post both scientific summary results and layperson summaries on CTIS within 6 months (paediatric) or 12 months (adult) of trial end, unless an extension has been granted in advance.[1] These are not voluntary transparency aspirations. They are legal obligations that were created to ensure that patients, doctors, researchers, regulators, systematic reviewers and health systems can rapidly access reliable information on the safety and effectiveness of medicines.

Patients were promised that the new law and new registry would deliver "high levels of transparency never seen before for clinical trials".[2] Yet the enclosed policy brief, based on the first-ever study of data quality and results reporting on CTIS,[3] shows that many sponsors are currently failing to comply with those requirements.

Only 116 of the first 234 European Phase II-IV drug trials required by law to report results on CTIS did so on time. Another 20 trials reported results late, and 98 trials had not fully reported results. In other words, more than half of early CTIS trial results were not made public as required by law.

Sponsors failing to upload documents is only part of the problem. The study found that many 'results' documents uploaded to CTIS did not actually provide usable results. Of 234 trials legally required to post results, 98 had failed to fully do so. These included 47 trials with no scientific results document, 4 trials with full scientific results but no layperson summary, and 47 trials whose scientific results documents failed to report participant numbers and/or outcome data for all salient primary endpoints.[3]

Some 'results' documents stated that results had never been analysed or were still being analysed. Others contained only vague narrative descriptions of outcomes or redacted data on study arms or key outcomes. Some 'results' documents even left unclear whether any participants had been enrolled in the first place.[3]

This is clearly not in the best interests of science, medical innovation, patients, or public health.

A registry that accepts such documents without quality assurance not only leaves large gaps in the medical evidence base. It also makes it difficult for regulators and the public to assess and track compliance.

We recognise that responsibility for authorising and supervising clinical trials lies with EU and EEA Member States. At the same time, EMA is responsible for maintaining CTIS,[4] and the design and operations of CTIS are central to whether the law delivers in practice.

The EMA Management Board, EMA and HMA have repeatedly shown that they can effectively improve clinical trial reporting. Strong engagement by EMA and some NCAs boosted EudraCT reporting rates. More recently, EMA put into place excellent support systems to help sponsors navigate CTIS, and the EMA Management Board initiated the process that led to the new CTIS transparency rules. We applaud that EMA informally supported the research cited in this letter, and we trust that the EMA Management Board and EMA continue to aspire to deliver "high levels of transparency never seen before for clinical trials."

The CTIS registry now contains more than 8,400 Phase II-IV drug trials. Over the coming months and years, each of those trials will have to report results. If EMA permits current non-compliance trends to persist, critical safety and effectiveness data for thousands of new medicines will remain hidden. Retrospectively addressing comparable compliance gaps within EudraCT required a major, long-term effort by EMA, NCAs and sponsors.

This is a unique window of opportunity to prevent problems from accumulating on CTIS in the first place by building an effective compliance system and fostering a strong compliance culture from a very early stage.

1. **Considering the urgency of the matter, we urge you to immediately reach out to the EMA Executive Director and the Chair of the HMA Management Group and encourage them to rapidly initiate measures to improve compliance.**
2. **In addition, we urge you to place this issue onto the agenda of the October 2026 meeting of EMA's Management Board and encourage the Board to direct EMA to work with NCAs and the European Commission to put in place a comprehensive action plan.**

The enclosed policy brief outlines practical measures that EMA could implement rapidly through the CTIS platform at low cost. These include:

- Proactively sending reminders to sponsors
- Making compliance-related data available and visible on CTIS
- Creating a quality assurance system for results documents uploaded by sponsors
- Setting up a clear workflow for managing requests to extend results reporting timelines
- Publicly tracking progress in improving compliance

Note that none of the proposed measures would generate an additional burden for sponsors that already comply with the law. Rather, they would help all sponsors meet obligations that already exist, and help EMA and Reporting Member States to more efficiently verify and monitor compliance.

Thank you for your time. Please let us know whether the EMA Management Board will discuss this issue.

Supporting organisations

1. AllTrials
2. BUKO Pharma-Kampagne
3. Consilium Scientific
4. EKPIZO

5. Ensemble Leucémie Lymphomes Espoir
6. Formindep
7. Groupe de Recherche et d Action pour la Sante (GRAS)
8. Health Action International (HAI)
9. JustTreatment
10. Laeger uden Sponsor
11. Melanoma Patient Network Europe
12. MEZIS
13. Prescrire
14. Salud por Derecho
15. Stichting Farma ter Verantwoording (Pharmaceutical Accountability Foundation)
16. Transparency International Global Health
17. TranspariMED
18. Universities Allied for Essential Medicines (UAEM) Europe
19. WECAN
20. World CUP Alliance

Enclosure: *Policy brief: Half of all clinical trials of drugs in Europe do not report results as required by law*

References

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2. Cooke E. End-of-year message from EMA's Executive Director. European Medicines Agency. 21 December 2022. https://www.ema.europa.eu/en/news/end-year-message-emas-executive-director-0
3. Bruckner T, Dike CE, Caquelin L, Freeman A, Aspromonti DA, DeVito NJ, Song Z, Karam G, Nilsonne G. Assessing Compliance with Reporting Requirements in European Phase II-IV Clinical Trials: A Cross-Sectional Observational Study. medRxiv. 2026. doi:10.64898/2026.04.03.26350111. https://www.medrxiv.org/content/10.64898/2026.04.03.26350111v1
4. European Medicines Agency. Clinical Trials Information System. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system