To: Dr Hugues Malonne, Head of Federal Agency for Medicines and Health Products (FAMHP)

Please respond to: Dr Till Bruckner, email: tillbruckner@gmail.com

Stockholm, 15 June 2026

Dear Dr Malonne,

According to the Clinical Trials Regulation (EU) No 536/2014, your agency is responsible for supervising and enforcing sponsor compliance with transparency requirements on the Clinical Trials Information System (CTIS), including the timely submission of scientific results and laypersons results under Article 37, for clinical trials for which your country acts as the Reporting Member State.

The Regulation is directly applicable in Belgium, and national law gives your agency the mandate and powers required to supervise and enforce compliance with its provisions.

As of November 2025, your agency was responsible for supervising 15 clinical trials that should have had results available on CTIS. Data from a recent academic study[1] show that sponsors had failed to make public the results of 4 (26.7%) of those trials in violation of the law.

Failures to rapidly make clinical trial results public can endanger patient safety, undermine public health, and slow down medical innovation.

Please respond to the following questions by 03 July 2026:

1. What action has your agency already taken to support sponsors' voluntary compliance with the legal requirement to make clinical trial results public on CTIS, and what are your agency's future plans in this regard?
2. What action has your agency already taken to sanction sponsors that have violated CTIS reporting requirements, and what are your agency's future plans in this regard?
3. How does your agency review the completeness and accuracy of the contents of scientific results and/or laypersons results documents that sponsors upload to CTIS? If your agency currently does not review uploaded results documents, please outline your agency's future plans in this regard.

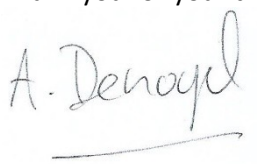
1 Bruckner T, Dike CE, Caquelin L, Freeman A, Aspromonti DA, DeVito NJ, Song Z, Karam G, Nilsonne G. Assessing Compliance with Reporting Requirements in European Phase II-IV Clinical Trials: A Cross-Sectional Observational Study. medRxiv. 2026. doi:10.64898/2026.04.03.26350111. https://www.medrxiv.org/content/10.64898/2026.04.03.26350111v1

4. Which of the trials that had not fully reported results as of November 2025 (see list further below) have by now made their full results public on CTIS as required by law?

We plan to make your agency's response public within the scope of an investigative journalism project led by Ms Ariane Denoyel with Blast! online investigative media, and an academic research project led by Dr Till Bruckner.

We will additionally share your agency's response with the 19 health groups from across Europe listed below, who support this request for information.

Thank you for your time, we look forward to hearing from you,



Ariane Denoyel
Investigative medical journalist
Paris, France

Till Bruckner
Postdoctoral Research Fellow
Karolinska Institutet, Stockholm, Sweden

Supporting organisations

1. AllTrials
2. BUKO Pharma-Kampagne
3. Consilium Scientific
4. EKPIZO
5. Formindep
6. Groupe de Recherche et d Action pour la Sante (GRAS)
7. Health Action International (HAI)
8. JustTreatment
9. Laeger uden Sponsor
10. Melanoma Patient Network Europe
11. MEZIS
12. Prescrire
13. Salud por Derecho
14. Stichting Farma ter Verantwoording (Pharmaceutical Accountability Foundation)
15. Transparency International Global Health
16. TranspariMED
17. Universities Allied for Essential Medicines (UAEM) Europe
18. WECAN
19. World CUP Alliance

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

Appendix: Violations of CTIS transparency requirements by clinical trials for which Belgium is the Reporting Member State as of November 2025

The table below provides an overview of the compliance issues among the clinical trials for which Belgium acts as the Reporting Member State.

Compliance issues	# Trials	Comments
Results reported fully but late	0	Scientific and laypersons results uploaded after the legal deadline for reporting results had expired[2]
No scientific results document uploaded	1	No scientific results document available on CTIS
Scientific results document lacks key data	3	Scientific results document on CTIS does not state the number of participants enrolled and/or some or all primary outcomes[3]
No laypersons results document uploaded	0	Adequate scientific results document available on CTIS, but no laypersons results document available

The table below lists clinical trials with compliance issues for which Belgium acts as the Reporting Member State.

CTIS trial ID number	Sponsor	Type of violation
2022-500228-31-01	Paradigm Biopharmaceuticals (USA) Inc.	Scientific results document lacks key data
2023-508528-36-00	Merck Healthcare KGaA	Scientific results document lacks key data
2023-506205-18-00	Institute Of Tropical Medicine	Scientific results document lacks key data
2022-501106-35-00	Eli Lilly & Co.	No scientific results document uploaded

Data accurate as of 10 November 2025. The protocol, dataset and code of the study identifying unreported clinical trials are publicly available on OSF (https://osf.io/sn4j2/overview) or upon request from Dr Till Bruckner.

2 The study took into account CTIS data on timeline extensions granted beyond the default 6/12 month reporting timeline.

3 The study narrowly assessed whether results documents contained information on two key elements: (1) the number of participants enrolled, and (2) outcomes for all primary outcome measures for the trial. These two elements are contained in Annex IV of the Regulation, which requires results documents to contain information on a total of 24 elements.