EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE.D.2/LA /eb/(2024)1583262

Subject: Ensuring full compliance with the Clinical Trials Regulation (EU) 536/2014 and its Delegated Acts from 31 January 2025.

Your Excellency,

I would like to bring to your attention that 30 January 2025 will mark the end of the three-year transitional period in the Clinical Trials Regulatory framework. Consequently, as from 31 January 2025, only the Clinical Trials Regulation (EU) 536/2014 (CTR) and its Delegated Acts will apply.

On 31 January 2022, the Regulation repealed the Clinical Trials Directive 2001/20/EC and national implementing legislations in the EU Member States. Article 98 of the Regulation, read in conjunction with Article 99, describes the applicability of a 3-year transitional period. This transitional period provides the possibility to transit the regulatory framework under which a clinical trial is conducted, from the Directive to the Regulation, from the day of the entry into application of the Regulation (i.e., 31 January 2022) until the end of the 3-year transitional period (i.e., until 30 January 2025), without the need to discontinue or put on hold an ongoing clinical trial.

From 31 January 2025 onwards, only the Regulation and its Delegated Acts will apply to all clinical trials. This means that clinical trials authorised under the Clinical Trials Directive 2001/20/EC and expected to be ongoing on and after 31 January 2025 must be transferred into the legal framework of the Regulation by 30 January 2025 using the Clinical Trials Information System (CTIS).

Should the clinical trials not have transitioned to the CTR by the end of the transitional period contemplated in Article 98 of the CTR, these trials are to be considered as non-compliant with the Regulation and:

- Sponsors may be subject to corrective measures by Member States pursuant to Article 77 of the Regulation.
- Member States would be in breach of the Regulation provisions should they refrain from taking the prescribed corrective measures after the transitional period has elapsed.

The Commission has been working closely with the Member States and the European Medicines Agency (EMA) to support commercial and non-commercial sponsors to transit. However, based on the figures that the EMA has retrieved from its databases, too many clinical trials still have to be processed. Thus, we foresee a surge of transitional trial applications, especially closer to the end date of the transitional period.

Therefore, it is critical that Member States urge sponsors' representatives in their country

to transit their trials from the Directive to the Regulation, from EudraCT to CTIS. At the same time, it is important that Member States have the capacity to process the transitional trial applications.

The National Contact Points sitting in the Clinical Trials Coordination and Advisory Group (CTAG) have committed to issue a decision on the transitional trial application within 22 days from receipt of the application, provided that Member States do not send Requests For Information. This pragmatic approach will allow a smooth transition without compromising the safety of the clinical trials participants and the robustness of the clinical trial data. This agreed process is reflected in the *Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation* ([1]) that CTAG members endorsed. It is important to materialise this commitment.

I appreciate the efforts that Member States have made up to this point. We are confident that encouragement from your side will strengthen the communication and outreach to sponsors to accelerate the transition towards the new regulatory framework and ensure compliance with the Regulation and its Delegated Acts.

Yours faithfully,

Sandra GALLINA

c.c.: BECKER Rainer, GIRAUD Sylvain, MISCHE Harald, ABDELALL Linda

([1]) Eudralex volume 10. Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation. Link : https://health.ec.europa.eu/document/download/10c83e6b-2587-420d-9204-d49c2f75f476_en?filename=transition_ct_dir-reg_guidance_en.pdf