

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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According to the Clinical Trials Regulation (CTR)¹ and the principles of good clinical practice², the sponsor has a responsibility to ensure the safety of clinical trial participants and the reliability of data even when activities are delegated to contract research organisations, including when activities are undertaken outside of the EU. There is, however, no legal requirement for activities to be undertaken by EU-based staff. Article 71 of the CTR defines the obligations for clinical trial sponsors and investigators, including the conditions for delegation of tasks. Furthermore, under Article 74 of the CTR, sponsors established in third countries must have a legal representative in the EU.

Member States are required to carry out inspections on their territory or in third countries to supervise compliance with the CTR³. The detailed arrangements for Good Clinical Practice inspection procedures are laid down in national implementing legislation, including the need for Member States to establish relevant procedures for arranging inspections outside the EU⁴. The European Medicines Agency also has a role in coordinating cooperation between Member States for inspections within and outside the EU. Hence, the necessary means to allow Member States to conduct inspections effectively and in a timely manner both within and outside the EU are in place.

¹ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. *OJ L 158*, pp. 1.

² <https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline>.

³ Article 78 of Regulation (EU) No 536/2014.

⁴ Implementing Regulation (EU) 2017/556 on detailed arrangements for the Good Clinical Practice inspection procedures pursuant to Regulation (EU) No 536/2014. *C/2017/1812. OJ L 80*, 25.3.2017, pp. 7.