

EN

E-004349/2025

Answer given by Mr Várhelyi
on behalf of the European Commission
(27.1.2026)

The Commission is aware of the scientific study mentioned by the Honourable Member¹. The Seventh Framework Programme for Research and Innovation² and Horizon 2020³ supported research on mRNA vaccines as part of a EUR 254 million research and innovation portfolio on cancer immunotherapy⁴.

Horizon Europe⁵ provides funding opportunities for research and innovation combining cancer immunotherapy and COVID-19 mRNA vaccines, e.g., under the EU Cancer Mission⁶, 'Health' Cluster 1⁷, and Innovative Health Initiative⁸.

The authorisation of clinical trials is a Member State competence. The Clinical Trials Regulation (CTR)⁹ provides maximum timelines for the authorisation procedure of clinical trials. Member States can shorten the assessment period should they consider the need. The Commission has proposed amendments to the CTR in the context of its proposal for an EU Biotech Act¹⁰ to accelerate authorisation of clinical trials and improve patients' access to medicines.

A company can apply for a marketing authorisation to the European Medicines Agency (EMA) with evidence to comply with the requirements of the EU legislation. This can include a justified request for accelerated assessment if the product is of significant public health interest¹¹. After assessment, where duly justified under an accelerated assessment, the EMA Committee for Medicinal Product for Human Use adopts a scientific opinion on whether the

¹ <https://www.nature.com/articles/s41586-025-09655-y>.

² <https://eur-lex.europa.eu/EN/legal-content/summary/seventh-framework-programme-2007-to-2013.html>.

³ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-2020_en.

⁴ IACT: <https://cordis.europa.eu/project/id/602262/reporting>; MERIT: <https://cordis.europa.eu/project/id/601939/reporting>.

⁵ https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en.

⁶ For example, see Mission Work Programmes 2023, 2024 and 2025: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-miss-2023-cancer-01-01>.

⁷ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/cluster-1-health_en; For example: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/HORIZON-MISS-2025-02-CANCER>.

⁸ <https://www.ihp.europa.eu/>. For example topic HORIZON-JU-IHI-2022-01-03: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-ju-ihp-2022-01-03>.

⁹ 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, 27.5.2014, pp. 1–76; ELI: <http://data.europa.eu/eli/reg/2014/536/oj>.

¹⁰ Proposal for a Regulation of the European Parliament and the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795, and (EU) 2024/1938 (European Biotech Act) COM (2025) 1022, 16.12.2025.

¹¹ Accelerated assessment: <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/accelerated-assessment>.

risk-benefit balance for the medicinal product in the requested indication is positive. Based on such recommendation, the Commission adopts a valid decision across the EU.