

Joint technical notice by the European Commission, EMA and HMA

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**TECHNICAL NOTICE TO SPONSORS REGARDING CONTINUOUS COMPLIANCE WITH THE EU
LEGISLATION FOR CLINICAL TRIALS¹ FOLLOWING THE WITHDRAWAL OF THE UNITED KINGDOM
FROM THE EU**

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a “third country”². The Withdrawal Agreement³ provides for a transition period ending on 31 December 2020. Since no extension was requested as of July 1 2020, there is no possibility for further extension beyond that date.

Therefore, sponsors of clinical trials conducted in the EU Member States are reminded of the legal situation applicable after the end of the transition period as described in the Commission Brexit readiness notice regarding Clinical Trials^{4,5}.

Most importantly, according to Article 13(2) of Directive 2001/20/EC, **the qualified person has to be established in the EU/EEA**^{6,7}. Investigational medicinal products used in clinical trials can be imported only after their batch-release has been certified by a qualified person in the EU. As of 1 July, 2020, based on data registered in the European Clinical Trials database (EudraCT), there are 250 trials where the QP is established in the UK and which have been authorised in at least one Member State other than the UK within the last 3 years (since 30 June, 2017). There are also other trials with a QP in the UK authorised before this date (n=3000). Sponsors of all ongoing trials need to establish a QP in the

¹ Directive 2001/20/EC is going to be repealed by Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (OJ L 158, 27.5.2014, p. 1). However, in view of the timelines set in its Article 99, this Regulation is not going to apply before the end of the transition period.

² A third country is a country not member of the EU.

³ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 (“Withdrawal Agreement”).

⁴ https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante

⁵ This letter, unlike the “readiness notice” does not address relevant separation provisions of the Withdrawal Agreement, nor the rules applicable to Northern Ireland after the end of the transition period.

⁶ Article 185 of the Withdrawal Agreement.

⁷ Further reference to EU in this text refers to EU/EEA

EU. Failure to do so could in the worst case result in discontinuation of trial treatment and thus jeopardise trial participants' safety.

In addition, according to Article 19 of Directive 2001/20/EC, **the sponsor of a clinical trial or a legal representative must be established in the EU**. As of 1 July 2020, there are 200 trials registered in EudraCT⁸ where the sponsor is established in the UK and the trial has been authorised in at least one Member State other than the UK within the last 3 years (since June 30, 2017). There are also other trials, where the sponsor is established in the UK, but which had been authorised before this date (n=750). In addition, for trials authorised in at least one Member State where the sponsor is established in a third-country and with a legal representative in the UK, the sponsor needs to establish its legal representative in the EU by the end of the transition period. At the end of the transition period, the sponsor or its legal representative has to be established in the EU for all ongoing trials. Failure to meet this requirement will be a breach of Directive 2001/20/EC and could trigger a request for corrective actions by Member State competent authorities.

⁸ As of March 2020, it is possible for Member States to include details in EudraCT, about the EU legal representative, for clinical trials where the sponsor is established in the UK. Following the end of the transition period, EudraCT will be adjusted to enable sponsors to enter details related to the EU legal representative for trials with UK sponsors (section B.2. of the CTA).