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Closed consultation

Consultation on the International Council for Harmonisation (ICH) E21 Guideline on the Inclusion of Pregnant and Breast-feeding Individuals in Clinical Trials

From: **Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)**

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We are analysing your feedback

Visit this page again soon to download the outcome to this public feedback.

Summary

The MHRA is consulting with UK stakeholders to gather feedback and comments on a new international guideline for the appropriate inclusion and/or retention of pregnant and/or breast-feeding individuals in clinical trials of medicines.

This consultation ran from **12:01am on 3 July 2025 to 11:59pm on 5 September 2025**

Consultation description

Pregnant and breast-feeding people are commonly excluded from clinical trials of new medicines. Consequently, many medicines have sparse information to allow informed decision making on the benefits and risks of using a medicine during pregnancy or breast-feeding. To address this, a new guideline (E21) has been prepared by an Expert Working Group (https://www.ich.org/page/efficacy-guidelines) (EWG) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The E21 guideline (https://database.ich.org/sites/default/files/ICH_E21EWG_Step2_Draft_Guideline_2025_0514.docx) highlights that in principle, pregnant and breast-feeding individuals should be eligible for inclusion in clinical trials of medicines that may be appropriate for their medical condition. The E21 guideline sets out the principles and conditions that should be met to allow enrolment and retention of pregnant and/or breast-feeding individuals into clinical trials and overall drug development plans.

The E21 guideline covers scientific and regulatory principles and ethical considerations for including pregnant and/or breast-feeding individuals, to protect the safety of the clinical trial participants and their child.

The MHRA welcomes views on the draft guideline from all UK stakeholders including patients and the public. You can provide comments and recommendations to the consultation as an individual or on behalf of an organisation (one response per organisation please) using the ICH Public Consultation Comments template (https://admin.ich.org/sites/default/files/inline-files/ICH_PublicConsultationComments_Template_Stakeholders_2020_1209.xlsx) and emailing it to ichconsultations@mhra.gov.uk. Please include ‘E21 consultation’ in the subject line of your email.

Following the consultation, feedback from the stakeholders within the UK and other ICH regions will be reviewed and discussed by the ICH E21 EWG directly. We do not intend to publish a full

response to this consultation, as we are not required to for this type of consultation.

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) became a full member of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in May 2022. ICH brings together global regulators and the pharmaceutical industry to achieve the harmonised development of safe, effective and high-quality medicines.

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