EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

← News

New guideline on inclusion of pregnant and breastfeeding individuals in clinical trials

4 June 2025

Recommendations will support better information on benefits and risks of medicines in this population

News Human

Share

EMA has released for public consultation a new guideline providing recommendations on how to include and/or retain pregnant and breastfeeding people in clinical trials. The goal is to ensure developers generate robust clinical data in those populations, so that these individuals and their healthcare providers can make informed, evidence-based decisions when using medicines.

This guideline, developed jointly by global regulators and medicines developers through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), marks a change in paradigm in the development of medicines in pregnancy and breastfeeding. It highlights that in principle, including pregnant and breastfeeding people in clinical trials should be considered for all medicines intended for people who can potentially give birth to children. It lays out the principles and conditions that should be met to ensure the safety of clinical trial participants, as well as their fetuses and babies.

Currently, pregnant and breastfeeding people are often excluded from clinical trials and those who become pregnant while participating in a clinical trial are frequently discontinued from the clinical trial. Less than 0,4% of all clinical trials currently submitted in the EU include pregnant people, and this falls to 0,1% regarding lactating individuals, according to data from the Clinical Trials Information System (CTIS).

As a result, product leaflets usually lack details about the benefits and risks of a medicine specifically in pregnancy and breastfeeding, requiring patients and healthcare professionals to make treatment decisions without this essential information. This can lead to suboptimal treatment decisions and potential harm. Meanwhile, the vast majority of pregnant people take medications, for example because of chronic diseases, infections, or pregnancy complications. The situation is similar in breastfeeding populations.

The guideline outlines the scientific and regulatory principles, as well as ethical considerations, for the inclusion

of pregnant and breastfeeding individuals in clinical trials, both pre- and post-authorisation. It encourages proactive planning and early consultation of medicine developers with regulatory authorities to ensure the safety and efficacy of treatments during pregnancy and breastfeeding.

The guideline is open for consultation until 15 September 2025. Comments should be provided using this template and sent to ich@ema.europa.eu.

Related documents

ICH E21 Guideline on inclusion of pregnant and breastfeeding individuals in clinical trials

Draft: consultation open

Consultation dates: 04/06/2025 to 15/09/2025

Reference Number: EMA/CHMP/ICH/149462/2025

English (EN) (1001.8 KB - PDF)

First published: 04/06/2025

View

Related content

ICH E21 Guideline on inclusion of pregnant and breastfeeding individuals in clinical trials – Scientific guideline

Medicines during pregnancy and breastfeeding

Clinical Trials Information System

Clinical trials in human medicines

External links

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): Public consultations

Contact point

Media enquiries

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

All other enquiries

please submit your request via the online form

Follow us on Bluesky

Share this page

Website data protection notice

Data protection at EMA

Search tips

Access to documents

Contacts

Send a question

EMA Service Desk (system support)

Services and databases

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000

How to find us
Postal address and deliveries
Business hours and holidays

RSS Feed

Bluesky

YouTube

LinkedIn

European Union agencies network

An agency of the European Union