Advice from College and FAMHP to sponsors and sites of clinical studies on the need for an updated ICH-GCP certificate for new submissions after the implementation of ICH-GCP (R3) on 23/07/2025

Date: 27 August 2025

This advice was endorsed by the College and the FAMHP via a written procedure.

## At the submission,

Till 31/12/2025:

ICH-GCP (**R2 or R3**) training should be documented (in the CV or by a GCP certificate) and should not be older than three years. Although formal training in ICH-GCP (R3) is not yet mandatory, the Agency expects that sites can provide evidence that investigators are aware of the existence of the guideline, particularly the sections relevant to their responsibilities, at least for studies approved after 23 July 2025.

From 01/01/2026:

CVs and/or GCP training certificates will need to refer to ICH-GCP (R3) training.