

Information for Clinical Trial Sponsors

As of **23 July 2025**, every investigator is required to have completed training on **ICH E6 (R3) – Guideline on Good Clinical Practice (GCP)**. **ICH GCP (R2) will not be accepted after 23 July 2025.**

The **State Institute for Drug Control (ŠÚKL)** and the **Ethics Committee for Clinical Trials (EC)** are aware that it is not feasible for all investigators to complete certified training on ICH GCP (R3) simultaneously. Therefore, we recommend that every member of clinical trial site teams engage in **self-study** of the ICH GCP (R3) document and strongly encourage them to review all materials and videos from the training organized by the **European Medicines Agency (EMA)**.

Certified training on ICH GCP (R3) must be completed by investigators as soon as it becomes available.

For the purpose of temporary training, we recommend:

- **Thorough self-study of the ICH E6 (R3)* document**, available on the EMA website: [☞ ICH E6 \(R3\) Guideline on good clinical practice \(GCP\)_Step 5](#)
- **Familiarization with expert explanations and presentations**, particularly the recorded training session organized by the European Medicines Agency (EMA) as part of the ACT EU initiative: [☞ EMA ACT EU workshop on ICH E6\(R3\) – Principles and Annex 1](#)

The entire training process (self-study) must be **properly documented** in the relevant clinical trial documentation, specifically:

- in the **TMF (Trial Master File)**, and
- in the **ISF (Investigator Site File)**,

for the purposes of Good Clinical Practice inspections.

We also request that clinical trial sponsors ensure that information about completed training (via self-study) is included in the **current CVs of principal investigators**, which form part of Section II of the documentation for initial submissions and all subsequent amendments.

***Note on Annex II:**

*Annex II expands the GCP framework particularly to advanced types of clinical trials, such as **pragmatic trials, decentralized trials, and trials utilizing real-world data**. The draft of this annex underwent a public consultation from **29 November 2024 to 28 February 2025** (Ref. EMA/CHMP/ICH/495903/2024), and its final version is expected in the course of 2025.*

Source: [ICH E6 Good clinical practice - Scientific guideline | European Medicines Agency \(EMA\)](#)