

## ADVICE FROM COLLEGE TO THE FAMHP VALIDATORS AND ETHICS COMMITTEES ON HANDLING A MISSING ICH-GCP (R3) TRAINING FOR THE PRINCIPAL INVESTIGATOR IN A SUBMITTED CTA

*Context: This issue has been discussed with the working group on 23/10/2025. The FAMHP and ECs have proposed the following approach which was approved by the College Board on 14/11/2025*

**Question :** What is expected of the FAMHP validator and the evaluating EC if the Principal Investigator's CV or ICH-GCP training certificate does not refer to ICH-GCP (R3) ?

What is expected from the FAMHP validator at validation?

- If ICH-GCP training certificate is valid (< 3 years old): No validation RFI is raised.
- If ICH-GCP training certificate is not valid (> 3 years old): Validation RFI is raised.

What is expected from the EC during the assessment and at the conclusion of Part II?

- Submission date **before 01/01/2026**:

*At the conclusion of Part II*, the EC may formulate a **recommendation** to inform the sponsor

- that the PI should follow a ICH-GCP (R3) training **before first participant is included**, and
- that this training should be documented in the **TMF**

- Submission date **after 31/12/2025**:

*During the assessment*, the EC **must** raise a **consideration**:

- to request the sponsor to either provide an updated CV or GCP certificate or a **commitment** that the PI will follow a ICH-GCP (R3) training **before the first participant is enrolled**,

*At the conclusion of Part II, and only if the sponsor did **not** answer the question raised during the assessment*, the conclusion may be a **conditional approval**.

Via the condition, the EC requests the sponsor to

- ensure that the PI follows a ICH-GCP (R3) training **before the first participant is enrolled**, and
- provide proof of this training via a **NSM (no assessment from the EC is expected)**.