

PLACE IN SITE FILE #10.2

## Information about Good Clinical Practice (GCP) training

All trial staff need GCP-training/certification, but at different levels depending on delegated roles.

- **Site investigator (international)**

Be sure that your current national GCP-training is updated according to ICH E6(R3) (from 06.01.2025).

If not, presentation of ICH E6(R3) as well as a training certificate can be found at <https://incept.dk/site-files/> (#10.2).

- **Site investigators (in DK)**

Take the course for investigators.

Can be found at <https://gcp-enhed.dk/e-learning/e-laering-for-investigatorer/>

- **Staff (medical doctors)**

Staff that screen patients and inform for consent need documented training/certification.

A specific course for this trial staff group is available at <https://incept.dk/site-files/> (#10.2). It consists of part 1 and part 2 and includes a certification.

It is available in Danish, and as English templates which national investigator will adapt to a national setting.

These will also be available at <https://incept.dk/site-files/> (#10.2)

- **Other trial staff (international)**

Document training/certification according to local/national requirement

- **Other trial staff (in DK)**

Take the course for project staff.

Can be found at <https://gcp-enhed.dk/e-learning/e-laering-for-investigatorer/>