

What if an Investigator of an ongoing clinical trial is absent for an extended period of time? How should this be handled?

Note: This procedure is only valid if the investigator leaves the research project for a long period of time but not definitively.

Chapter 4 of the ICH-GCP defines all the Investigator's roles and responsibilities. In particular, in conducting a clinical trial the Investigator is responsible for:

- Ensuring that the clinical trial is conducted in compliance with GCP, the applicable regulatory requirements, and the study protocol;
- Protecting the rights, safety, and welfare of the persons under his care during the clinical trial;
- Controlling drugs, biological products, and devices under investigation.

In addition, even if the Investigator has designated individual members of the clinical trial team to perform critical trial-related procedures and/or to make important trial-related decisions, the Investigator must guarantee an appropriate supervision of the conduct of the clinical trial at the investigational site at any time.

Therefore, an Investigator must designate a replacement (a new investigator), if he/she leaves the trial site for a temporary but extended period of time for some reason (e.g. sabbatical leave) and if during this period he/she won't be able to fulfill all Investigator's responsibilities, nor guarantee an appropriate supervision of the conduct of the clinical trial. The trials subjects must be informed of the change.

This is defined as a substantial change and must be submitted as amendment to the ethics committee and authorised before being implemented. This requires a cover letter with the explanation of the absence, the expected date of return of the investigator to the investigational site and the evidence of qualifications of the new investigator.

If the investigator leaves the research project definitively, the change of investigator and the study documents affected by the change (CV and GCP certificate of the new investigator, informed consent form, protocol signed by the new investigator, clinical study agreement, etc.) must be submitted to the ethics committee for authorisation as amendment (ClinO Art. 29).