

Who Can Be an Investigator?

Qualifications and experience

The investigator must be suitably qualified and have the appropriate experience. An up-to-date CV will be requested by the sponsor: this should describe the investigator's current appointment as well as providing any other relevant evidence of suitability to undertake the trial. Knowledge of GCP and the appropriate regulatory requirements will also be required, although new investigators can learn this.



Time and availability

The investigator must have time to do the study. Time is needed

- for regular meetings with the sponsor's monitor
- to identify and screen suitable subjects
- to spend with trial subjects, as appointment times will be much longer than usual
- to brief research team members and review the progress of the trial
- to complete paperwork: trials generate numerous documents
- to spend with auditors and inspectors.

An investigator should also

- have the appropriate facilities and equipment
- have suitable co-workers
- have a reliable number of suitable subjects to enter the trial
- be committed to complying with the requirements of GCP.



Relevant Extracts from the ICH GCP Guidelines

4.1.1

The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).

4.1.3

The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.2.2

The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3

The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

5.6.3

The sponsor should obtain the investigator's/ institution's agreement:

(a) to conduct the trial in compliance with GCP, with the applicable regulatory requirement(s) (see 4.1.3), and with the protocol agreed to by the sponsor and given approval/favourable opinion by the IRB/IEC (see 4.5.1);