

GCP: Investigator Responsibilities

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Investigator Responsibilities

- Qualifications & agreements
- Resources
- Responsibilities to the subject
- Ethics
- The protocol
- The IMP & randomisation
- Informed consent
- Reports & records
- Safety reporting

Responsibilities

The following principles are from ICH GCP
Topic E6 and apply to clinical trials of
Investigational Medicinal Products

Why is it important?

- This may be an unlicensed drug
- Staff may be unaware of their responsibilities

Qualifications & Agreements

The Investigator should be:

- Qualified by education, training & experience
 - CV's, training records, other relevant documentation
- Thoroughly familiar with the protocol & medicinal products
- Comply with GCP and applicable regulations

Qualifications & Agreements

- Permit
 - monitoring and audit by the sponsor
 - inspection by regulatory authorities
- Maintain a delegation list

Example delegation log

Name	Role	Responsibility (codes)	Date started work on The trial	Date Stopped work on the trial	Sample signature	Initials
Julie Munch	Co Investigator	A, E, F, G, H, I, J, K, L, M, N, O, P, Q, RR, SS, SSS, TX, Y, D B, Z	October 2002			J.M
Samantha Day	Co Investigator	A, E, F, M, N, O, P, Q, RR, SS, SS S, T, X, Y, AA , LL, OO, DB	June 2003			S.D
Codes						
A - decide on eligibility	B - administer informed consent	C - prescribe drugs				

Qualifications & Agreements

- Ensure that all persons assisting with the trial are adequately informed about the
 - protocol
 - IMP
 - their duties and functions

Resources

The Investigator should:

- Be able to demonstrate potential for recruiting the required number of subjects.
- Have sufficient time to properly conduct and complete the trial within the agreed period.
- Have available adequate facilities and qualified staff to conduct the trial properly and safely

Medical Care Of Trial Subjects

- A qualified physician who is an investigator (or sub-investigator) should be responsible for all trial related medical decisions
- During and following participation the Investigator should ensure adequate medical care for any Adverse Events (AEs).

Medical Care Of Trial Subjects

- The Investigator should make a reasonable effort to ascertain reasons for withdrawal from the trial (although a subject is not obliged to give reasons).

Ethical Approval

Before initiating the trial there should be **written and dated** approval/favourable opinion from the Ethics Committee for the

- protocol
- consent form
- amendments

Compliance with Protocol

The Investigator should

- conduct the trial in compliance with the approved protocol
- sign to confirm their agreement.
- not implement any deviation from the protocol without prior approval/favourable opinion of the IEC and the sponsor

Compliance with Protocol

- The Investigator should document and explain any deviation from the protocol
- The Investigator may implement a deviation from the protocol to avoid an immediate hazard.

Investigational Medicinal Products (IMP)

- Investigator has responsibility for IMP accountability at trial site
- Some/all IMP duties at the trial site may be assigned to suitably qualified pharmacist etc.
- Records must be maintained
 - delivery
 - inventory
 - use
 - destruction

Investigational Medicinal Products (IMP)

- Storage of the IMP should be as specified by the sponsor / regulatory requirements
- The IMP should only be used in accordance with the protocol
- The Investigator (or designee) should explain the correct use of the IMP to each subject.

Randomisation

- The investigator should follow the trial's randomisation procedures as detailed in the protocol

Records and Reports

The Investigator is responsible for:

- accuracy
- completeness
- legibility
- timeliness

of the data reported to the sponsor


Records and Reports

- Data reported on CRFs, from source documents should be consistent with the source documents or discrepancies explained

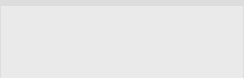
Records and Reports

- Corrections should be
 - dated
 - initialled
 - explained (if necessary)
 - should not obscure the original entry (audit trail)

Scrubbing out?

(a) 12  2008

Over writing?

(b) 12  2008

Tippex?

(c) 12/0  /2008

Line through, add correction, initial & date?

08 SAT 31/OCT/2009
(d) 12/ ~~08~~ /2008

Records and Reports

- Records of corrections should be retained
- All trial documents should be maintained as specified in ICH GCP E6, Section 8.

Records and Reports

- Essential documents ~ retained for the prescribed time or as agreed by the sponsor
 - Trial Master File (TMF) and Investigator (Site) File (ISF) should be established at beginning of the trial
 - ICH E6 (Section 8), SOPs/WPD inform which documents must be kept in the TMF and/or ISF
- Measures to prevent accidental or premature destruction of the documents
- Financial aspects of the trial should be documented in an agreement between the sponsor and investigator or institution

Records and Reports

- Trial related records must be made available to the
 - Monitor
 - auditor
 - IEC or regulatory authority
- The investigator should submit written summaries of the trial status to the sponsor at defined intervals

Safety Reporting

- Investigators must report Serious Adverse Events to the sponsor as soon as they become aware of the event

Other Staff

- PI ~ overall responsibility

BUT

- All staff must comply with GCP
- Staff should only perform tasks delegated to them
- Staff should ensure that their details are available to the Investigator
- Staff should maintain appropriate confidentiality at all times

GCP: Investigator Responsibilities

Any questions?