The role, duties and responsibilities of clinical trials personnel

Sponsor

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Mwanza 11th-14th June 2012

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1) Sponsor

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

2) Sponsor-Investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

(*Guideline for GCP-CPMP/ICH/135/95*)

Sponsor's responsibilities 1/3

Quality Assurance and Quality Control

5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access to all trial related sites, source data/documents , and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

(sec n. 5 of *Guideline for GCP-CPMP/ICH/135/95*)

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Sponsor's responsibilities 2/3

Quality Assurance and Quality Control

5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

5.1.4 Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.

(sec n. 5 of *Guideline for GCP-CPMP/ICH/135/95*)

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Sponsor's responsibilities 3/3

A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO (Contract Research Organization) , but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

(*Guideline for GCP-CPMP/ICH/135/95*)

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Sponsor's duties 1/2

- Medical expertise
- Trial design*
- Trial management, data handling and record keeping
- Investigators selection*
- Allocation of responsibilities
- Compensation to subjects and Investigators in case of any damage (Insurance policy)
- Financing
- Notification /submission to Regulatory Authorities*
- Confirmation of approval by IRB/IEC*
- Information on Investigational Product(s)

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Sponsor's duties 2/2

- Manufacturing, Packaging, Labelling, and Coding Investigational Product(s)
- Supplying and Handling Investigational Product(s)
- Record Access
- Safety Information
- Adverse Drug Reaction Reporting
- Monitoring*
- Audit
- Premature Termination or Suspension of a Trial
- Clinical Trial/Study Reports

(all duties marked as * usually are delegated to the CRO)

(*Guideline for GCP-CPMP/ICH/135/95*)

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To be continued …..