GCP inspections
and
Phase I (F.I.M.) clinical trials

Pierre Henri BERTOYE
Clinical Trials Inspection Unit
French Health Products Safety Agency

GCP and Phase I (FIM) clinical trials
Safety of clinical trial subjects

- **4 main parts:**
  - Preparation of the protocol
  - Clinical environment for conducting the study
    - Investigator's team
    - Clinical trial Unit organisation
  - IMPs : quality and proper use in the trial
  - Rising dose design :
    - Further subjects cohort safety depends on :
      - the collected and reported safety results from the previous cohort(s) => then the availability and credibility of these results
      - Suitability of the dose escalation scheme (…)

GCP and Phase I (FIM) clinical trials Conducting inspections in Phase I units

- **2 types of inspections**
  - **System inspections**
    - **To give confidence on the system**
      - **Authorization / accreditation of the site**

        Authorisation system : 3 M.S.

        Accreditation system : 2 M.S.
      - **Acceptance of data submitted in M.A. dossiers without requesting trial inspection**
  - **Trial inspections**
    - **Specific questions on a trial / safety or quality of data**

EMEA GCP Inspection Services Group

Guidance for conducting GCP inspections in phase I units

Guidance no.: INS/GCP/3/V

ANNEX V

TO GUIDANCE FOR CONDUCTING GCP INSPECTIONS REQUESTED BY THE EMEA:

PHASE I UNITS

GCP Inspection Services Group

Applies to: EMEA, EU/EEA Inspectorates

Summary of scope: This guidance compiles the main aspects that are to be verified at phase I units during a GCP inspection requested by the EMEA

Keywords: GCP Inspections, Phase I	Restricted
Supersedes: N/A	

Finalisation	Date
Adoption by the Ad Hoc Meeting of GCP Inspections Services	2 March 2005
Revision	09 November 2006
GCP Inspection Services Group	

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 95
E-mail: mail@emea.europa.eu http://www.emea.europa.eu/

Contents

GCP and Phase I (FIM) clinical trials Considerations and concerns

Clinical environment for conducting the study Personnel and facilities

- Investigator's team
  - Qualification, experience, agreements (GCP § 4.1.)
    - Experience to assume responsibility for the proper conduct
      Protocol and contract understood and agreed
      France : PTCL also reviewed by a pharmacologist
    - With basic and advanced life support training
  - Adequate resources (GCP § 4.2.)
    - Adequate staff rota, medical and ancillary-medical cover
      France : PTCL review by a MD qualified / resuscitation
  - Adequate medical care of Trial Subjects (GCP § 4.3.)
    - Management of adverse events, maintenance of subjects

GCP and Phase I (FIM) clinical trials Consideration and concerns

Clinical environment for conducting the study
Personnel and facilities

- Clinical trial Unit organisation: Emergency
  - Procedures and equipment
    - Alarm points and procedures; contact numbers to subjects
    - Emergency trolley(s)
    - Beds: tilted / adjusted for height
  - Immediate access to I.C.U. facilities

    France : Existing agreement CT unit and I.C.U.
    Dosing periods to be known by the I.C.U.
    Adequate training and experience to manage emergencies: simulation

GCP and Phase I (FIM) clinical trials Conclusions

- **No current EU guidance on**
  - Investigator's team qualification, experience
  - Adequate resources (medical/ancillary cover)
  - Emergency procedures
- **National initiatives**
  - Authorisation (3 M.S.) / accreditation (2 M.S.) of phase I units
  - Categorisation of phase I units
    CT with Potential HRMPs / other trials
- **Guidance on Phase I unit / trial inspections**
  - To be revised to differentiate system and trial inspections
  - Specifications for specific phase I: F.I.M. / HRMPs trials
- **No GCP inspection program coordinated at EU level**
  Except for BE studies in the context of evaluation