GOOD CLINICAL TRIAL PRACTISE, GCTP

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GOOD CLINICAL TRIAL PRACTISE

History

- Citrus fruit study (skjörbjugg)
- Vaccination
- GMP – 1960-ties
- GLP – 1980-ties
- GLTP – Thalidomid – Neurosedyn
  - 1977 – Proposal from FDA
  - 1989 – Nordic guidelines
GOOD CLINICAL TRIAL PRACTISE

GCTP is an international ethics and scientific standard for

– Planning
– Conducting
– Documenting and
– Reporting
clinical studies in man
GOOD CLINICAL TRIAL PRACTISE

First Nordic Guidelines in 1989
- Medical Products Agency LVFS
  2003:6

Objectives
- To protect the interest of the patient
- To assure quality inb research
GOOD CLINICAL TRIAL PRACTISE

Purpose:

- Approval for registration and marketing
- Prove scientific hypothesis
- Utility of the drug when used in the general population
- Marketing – multicentre seeding trials
ICH-GCP
International Conference of Harmonization

Cooperation between USA, Japan and Europe of pharmaceutical industry, regulatory agencies and academic institutions

First meeting held 1989
ICH-GCTP

Objectives:
- Avoid unnecessary studies
- Studies should be carried out anywhere
- Minimize studies in animals
- Faster drug development
- In the future: Drugs are approved for a region

- www.ich.org
ICH-GCTP- Main components

- Informed consent
- Ethic committee approval
- Sponsor must provide SOP for planning, conduct, closure and report
- Responsibilities of sponsor and investigator
- Monitoring procedure
- Auditing procedures
- Documentation
- Archiving of documents
A clinical drug trial - A chain of thoughts and decisions

- Study objective
- Main question
- Hypothesis
- Study design
- Inclusion criteria
- Exclusion criteria
- Efficacy end point
- Safety (AE and ADR)
- Statistics
- Monitoring
- Data management
- Analysis and reporting
- Conclusions
CLINICAL DRUG TRIAL

STUDY PHASES

Phase 0
Chemistry
Animal studies

Phase 1
Healthy volunteers (30-100)
Pharmacokinetics

Phase 2
Open study in patient(<1000)
Pharmacokinetics in pt~ 5000

Phase 3
Large patient studies (>10000)

Phase 4
Post marketing studies
EXPLANATORY STUDIES

CONFORMATION STUDIES
GCTP: Study protocol

- Introduction and rationale
- Study objectives
- Study design
- Time schedule
- Patent numbers
- Patient selection
- Inclusion criteria
- Exclusion criteria
- Withdrawal criteria
- Blinding of the study
- Breaking randomisation code
- Investigated products
- Packaging and labelling
- Storage
- Administration route
- Compliance checks
- Drug accountability
- Study procedures
- Adverse events
- Case report form
- Efficacy and safety
- Statistical analysis
- Ethic responsibilities
- Insurance and liability
- Study monitors
- Audit and inspection
- Financial agreement
- Publication
- Completion of study
STANDARD OPERATING PROCEDURES FOR GCTP

Consider:

- GCTP regulations
- FDA
- ICH
- Company demands
- Legal demands
- Insurance demands
CASE RECORD FORM, CRF

- Master information
- Not possible to change printed text
- No empty spaces – Lacking data = NA
- Written text can be changed
  - what is wrong and add the right text
  - Signum with date (monitor’s mantra)
Clinical Trial Actors (GCTP)

- Auditör
- INVESTIGATOR ↔/→ SPONSOR
- Monitor (CRO/Hospitalpharmacy)
Monitoring

Assure the security and well-being of patients and volunteers

CRF is correct, complete and traceable to Master documents

The study is performed according to GCTP and study protocols with amendments

Audit of the study site
GOOD CLINICAL TRIAL PRACTISE

GCTP guarantees that

"Studies are scientifically and ethically:

- Designed (study protocol)
- performed
- recorded (CRF)
- finished
- reported and documented
Jag har utstått många prövningar

varav en klinisk
GOOD LABORATORY PRACTISE

- Animals
  - Housing
  - Heritage
  - Feeding
  - Timing
  - Type of food
  - Light-dark circle
  - Aggression