GOOD CLINICAL TRIAL PRACTISE, GCTP

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GOOD CLINICAL TRIAL PRACTISE

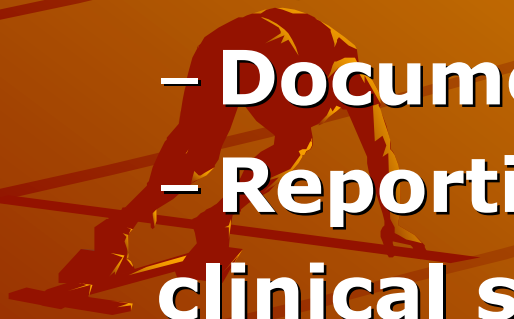
- ***History***

- **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

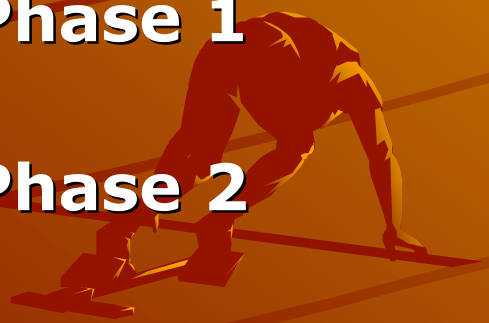
- Informed consent
- Ethic committee approval
- Sponsor must provide SOP for planning, conduct, closure and report
- Responsibilities of sponsor and investigator
- Monitoring procedure
- Auditing procedures
- Documentation
- Archiving of documents

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 studie 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