Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

MULTISITE STUDIES

GLP-Seminar 16.9.2014 Paula Korhola

MULTISITE STUDIES

Definition of a multisite study
= several test sites

A GLP Study is considered as a multisite study, if it's done:

- in a part of different/separate organisation of the company
- different countries
- same organisation but different location (city, etc.)
- same organisation but different department

MULTISITE STUDIES

- Guidance for Multisite Studies:

The Application of the OECD Principles of GLP to the organisation and management of multi-site studies (2002, OECD GLP Consensus document no 13)

OECD Principles of Good Laboratory Practice

MULTISITE STUDIES

- Examples of multisite studies:

Residual studies (field studies)
- Test site: field studies
- Test facility: analytical laboratory

Toxicology studies:
- Test facility: Animal testing centre
- Test sites: analytical laboratory, histopatology laboratory etc.

Test facility and test sites must be in GLP-compliance

MULTISITE STUDIES

ROLES IN MULTISITE STUDIES

- Sponsor
- Management of test facility and test sites
- Study Director (SD) and Principal Investigator/s (PI)
- Quality Assurance: lead QA and QA/s for test site/s
- Personnel conducting the study

MULTISITE STUDIES

ROLE OF THE SPONSOR

- Decides to conduct a multisite study and facility
  - Note: Sponsor itself can be a test facility
  - GLP-compliance; applicable national requirements

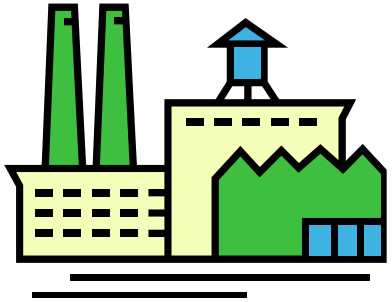
- ***Sponsor aware: the whole multisite study including test facility, test sites, operations, staff involved is a subject to control of the SD***

MULTISITE STUDIES

MANAGEMENT FOR TEST FACILITY AND TEST SITES

Responsibilities of Test Facility:

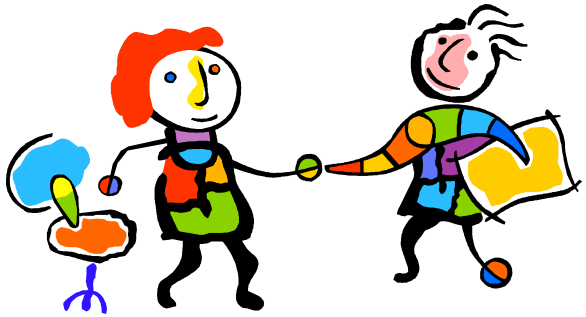
- Appoints SD
- Approval of test sites
- Appointment of leading QA and informing test sites of lead QA
- Equipments and expertise



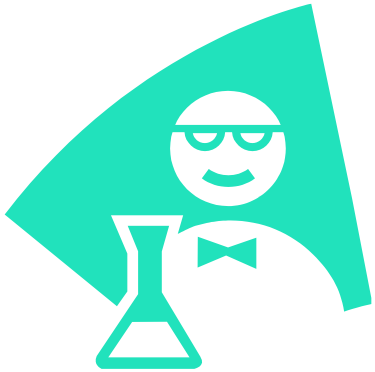
MULTISITE STUDIES

RESPONSIBILITIES OF TEST SITE MANAGEMENT

- Resources
- Selection of Principal Investigator (PI)
- QA; either own dedicated QA or Lead QA
- Procedures for replacing PI, if needed, in place
    - replacement of PI is done through Amendment
    - Sponsor and Test Facility must be informed, SD involved in replacement



MULTISITE STUDIES



- RESPONSIBILITIES OF THE Study Director, SD

- **ONLY ONE SD**!
- Ensures resources: personnel, equipments etc.
- Responsible for the Study Plan and Report (incl. Test sites)
- Makes changes into the Study Plan; approval and commenting (Amendments, Deviations)
- ensures that personnel has all the information regarding the Study: copies of Study Plan, SOPs, changes will be informed, etc.
- Developes acting communication system between test sites and PIs
- ensures that lead QA and site QAs have audited the study according respective areas
- Ensure that Study Report is submitted to lead QA for inspection
- Signs Study Report: indication of responsibility, extent of compliance of the study with GLP

MULTISITE STUDIES

RESPONSIBILITIES OF Principal Investigator (PI)

- ”Deputy” of SD at the test site: responsible for the study at the test site and compliance with GLP
- Communicates with SD (documentation of communications!)
- Responsibility must be documented: signs Study Plan and phase Study Report if separate one
- Informs SD of any deviations
- Ensures that all information regarding the study phase under his/her supervision is transferred to the SD

MULTISITE STUDIES

QUALITY ASSURANCE

Lead QA:

- ensures test sites QAs, plans for study audits
- inspects the Study Plan
- inspects the Study Report and confirms GLP compliance
- keeps a copy of Study Plan
- ensures roles of PIs and audits done at test sites
- ensures the QA Statement covering the whole study including phase studies
- communicates with test site QAs - documentation

MULTISITE STUDIES

- QUALITY ASSURANCE

Test site QA:

- inspects Study Phase Plan for the test site
- keeps a copy of Study Plan
- audits study phase done in the test site
- reports PI, test facility and test site management, SD, lead QA
- co-operation with Lead QA – documentation!

MULTISITE STUDIES

- MASTER SCHEDULE

- Responsibility of management of test facility and test site

- Multisite studies must be listed in the master schedule and linked/referred to the master study number, if separately numbered
- SD and PIs must be mentioned in the master schedule
- Dates of beginning and finishing the study included
- Date of archiving the study, if relevant

MULTISITE STUDIES

- STUDY PLAN

ONLY ONE STUDY PLAN!

Includes:

- test facility, test sites, Study phases
- names of SD, PIs
- addresses, contact information
- description how information is collected and provided to SD
- how archiving is done and by whom
- approved by SD and test facility management, verified for GLP assurance by QA
- responsibility of SD

MULTISITE STUDIES

- STUDY REPORT

ONLY ONE STUDY REPORT!

- Responsibility of SD

Includes: - all results from the study; compilation of phase study results including Amendments and deviations
- phase report can be as a separate part made by PI
→ statements of GLP compliance and QA
- signed and dated by SD; extent of GLP compliance must be described
- description of archiving: whose responsibility, where
- any Amendments: SD (PI)

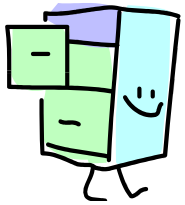
MULTISITE STUDIES

Archiving:
Responsibility of SD

Protection of integrity, also during study

Part of Study Plan and Report

If test facility is not able to archive→ material must be transferred to a GLP compliant archive



Outsourced archives: must be in GLP compliance!

Procedures in case of:
- Crisis in archive
- Test facility/test site is turned down, out of business
- Archive is turned down

MULTISITE STUDIES

SUMMARY

One SD
One study number
One Study Plan
One Study Report
One QA – Lead QA

Documentation of communication between SD, Lead QA-QAs, PIs