

VICH GCP Workshop 17. – 18. Sep. 2001, Munich

Expertise required for Monitors, Investigators and Contract Research Organisations

K. Hellmann, KLIFOVET AG, Munich

Purpose of VICH GCP

The purpose of the VICH GCP is to establish guidance for the conduct of clinical studies that ensures the accuracy, integrity and correctness of data. Due regard should be given to the welfare of the study animals, the effects on the environment and the study personnel and to residues in the edible products derived from food-producing study animals. This will lead to universal acceptance.

Persons involved

- Monitor
- Investigator
- CRO (Sponsor)

The Monitor

- Expertise requirements
- Responsibilities
- Practical Implications
- Feasibility
- Conclusion

Expertise of Monitor

- Trained in quality control techniques and data verification procedures
- Scientific training and experience to knowledgeably oversee a particular study
- Understand all applicable protocol requirements and determine whether it was conducted in accordance with it and relevant SOP's
- Very good communicator: principal link between Sponsor and Investigator

Monitor Responsibilities

1. To have expertise and time available
2. To select investigators
3. To ensure that the investigator and staff are trained and comply with the protocol, regulatory requirements and SOP's
4. To visit Investigator(s) before, during and after the study
5. To ensure that informed owner consent is obtained
6. To ensure that data is recorded legibly, completely and accurately and missing data /corrected data are fully explained
7. To confirm drug accountability incl. disposal
8. To review data and determine if protocol has been followed
9. To record all contacts
10. To confirm Investigator compliance to GCP
11. To submit summary report of contacts, visits and activities
12. Not to bias data collection process or outcome of study

Practical Implications and Feasibility

1. Full time Monitors are available
 - Internally within the Industry
 - Externally within CRO's or self-employed
2. May need further training to comply
3. Demanding areas of activity
 - To ensure the conduct and quality of others
 - Being primary link between Inv and Sponsor
 - Having responsibility for the final success

Conclusion for Monitors

- The increased requirements for Monitors within VICH GCP result in:
 1. Standard requirements for Monitors
 2. Frequent visits to Investigator(s) and greater time commitment
 3. Better quality studies?
 4. Considerable escalation in costs

The Investigator

- Expertise Requirements
- Responsibilities
- Practical Implications
- Feasibility
- Conclusion

Expertise of Investigator

- Sufficient knowledge, scientific training and expertise (postgraduate qualifications)
 - To conduct clinical studies to investigate the effectiveness and in-use safety of inv. vet. products in the target species
 - To be responsible for all aspects of the conduct of the study
 - To be familiar with the background and requirements of the study

Investigators Responsibilities

1. To have expertise, appropriate qualifications and time
2. To know and comply with the protocol
3. To train own personnel before any action on study
4. To select the right patients
5. To obtain an owner consent before any action on animal
6. To care for housing, feed and the welfare of the animals
7. To provide well-maintained facilities and equipment
8. To be able to record data legibly and accurately
9. To account for the drug supply, use and disposal
10. To observe and report AE's
11. To handle samples appropriately
12. To record all contacts and maximise data quality
13. To archive data securely

Practical Implications and Feasibility

- Expertise is achievable by training, but no commitment nor availability
- Why do investigators refuse to act as such?
 1. Lack of time/availability
 2. No interest in investment
 3. Lack of interest
 4. Vast need for documentation
 5. Requirements of GCP
- Feasibility: difficult

Conclusion for Investigators

- The increased requirements and responsibilities for Investigators result in:
 1. Very limited number of investigators interested and prepared to comply
 2. No top experts (time and/or commitment) ready to act as such
 3. Longer periods to run studies/develop products
 4. Ever increasing high costs

Contract Research Organisations

- Expertise requirements
- Responsibilities
- Practical Implications
- Feasibility
- Conclusion

Expertise Requirements for CRO's

- Dependent on the contract and responsibilities undertaken
 - Delegation by the Sponsor in writing
 - e. g. Responsibility List
 - CRO has to comply with all the requirements of the Sponsor within GCP
- Ultimate responsibility for quality and integrity of study data always resides with the Sponsor

CRO's Responsibilities

Employees of CRO's may act as

1. Investigator
2. Monitor
3. Sponsor

In all cases the Individual has to comply with GCP dependent on the responsibility undertaken

Sponsor Responsibilities (or CRO)

1. Initiate, manage and finance the study
2. Provide sufficient scientifically valid information on the effectiveness and safety of the inv. vet. product and ongoing updates
3. Determine that there are no risks on environment, welfare, ethical and scientific grounds
4. Obtain ATC's and report all AE's
5. Select Investigator(s) and Monitor(s)
6. Prepare protocol, arrange for SOP's
7. Multicenter studies: guarantee uniform instructions (in different languages), provide data collection system, facilitate communication
8. Provide product and account for drug usage
9. Ensure humane care and if relevant, proper disposal of animals
10. Maintain and archive study documentation, arrange for study report
11. Implement quality audit procedures to ensure quality and integrity

Practical Implications and Feasibility

1. Sponsor / CRO relationship:
 - Written contract
 - Detailed description of responsibilities
2. CRO:
 - Update expertise dependent on services offered / provided
 - Update SOP's

Conclusion for CRO's

- The general increase in requirements and responsibilities for services provided by CRO's will result in:
 1. Limited number of highly specialised CRO's
 2. Detailed contracts between Sponsor and CRO's
 3. Longer periods to run studies/develop products
 4. Ever increasing workload and costs for studies

FINALLY

- Expertise requested by GCP will lead to high quality studies with data integrity and accuracy if GCP
 - will be applied by all the industry
 - will be the recognised standard both scientifically and within veterinary practices
 - will be checked by audits / inspections
 - will be highly appreciated by all authorities and in case of non-compliance studies will not be accepted
- Then GCP will lead to universal acceptance of studies



Thank you!

KLIFOVET AG
www.klifovet.com

Tel: +49 89 58 00 82 0

Fax: +49 89 58 00 82 15

Email: klaus.hellmann@klifovet.com