Xournals

Academic Journal of Veterinary Sciences

ISSN UA | Volume 01 | Issue 01 | January-2019

Laboratory Approaches in the Field of Veterinary

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Available online at: www.xournals.com

Received 13th August 2018 | Revised 3rd October 2018 | Accepted 6th December 2018

Abstract:

For the global marketplace, development and regulatory approval of veterinary medicines by the clinical studies that plays a vital role. From clinical research to clinical practice, transfer the knowledge by generating the data from veterinary clinical trials in human and veterinary settings. When product will do work with efficacy and will do no harm (safety), it means of product achieve the success in obtaining the authorization to market in the target population and under the conditions of future use. For veterinary clinical studies, requirements of regulatory that have been developed over the last few years. From Food and Drug Administration (FDA), take the Good Clinical Practice (GCP) guidance documents that provide principle and procedures for safeguard data reproducibility, integrity, and reliability. Clinical studies use in veterinary medicine that has been increasingly common and progresses with some new challenges. In this paper, discuss the quality control and quality assurance for veterinary clinical studies.

Keywords: *Veterinary Medicine, Clinical Studies*

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Introduction

Damage to the economic, environmental and social factors by the diseases of animal and in some other cases, it can also threaten the life of a human. Due to the impacts of global changes, many zoonotic infectious disease display global-scale features and many threats are arising out of the livestock industry. On infectious disease, increasing the cost of developing and maintaining research infrastructure due to the higher sophistication of progression of an upgrade of safety regulations as well as technical research approaches for bio-contained research facilities. Continue running the cost of research on bio-contained facilities that is scarce. For this reasons, in 2011, launched a global strategic alliance for the management of research on the animal's infectious disease (Ducrot *et.al* 2016).

Veterinary clinical studies have required the regulations that have been developed over the last few years (McPhee and Reimers 2006). To determine the disease of an animal, using a medical intervention (treatment, device, approach) that are designed by veterinary clinical studies which are safe and effective after applying on the client-owned animals. With spontaneous disease (as opposed to experimentally induced models), performed such studies in veterinary patients but performed occasionally studies in healthy client-owned dogs (such as for disease prevention). To evaluate a novel therapeutic or device by increasing the number of clinical trials for the benefits of animal health in veterinary patients that are prior to initiation of human clinical trials (called as translational and comparative trials). 'One health' research field contains the important component that is veterinary clinical trials in which affecting and advancing global health by the complex health interaction of human, environment, and animals (Davies *et.al* 2017).

For clinical study monitor, require the current best practice that will discuss in this paper. In a clinical study, a monitor plays a key role that is not sufficient for recognized, it will require the activeness in all aspects of the clinical study. Clinical studies of veterinary are currently represented by the International Conference on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH) Good Clinical Practice (GL9) that gave the guidelines for safety of Veterinary. In VICH GL9, developed the guidance for safety purpose in veterinary clinical studies that contain some terminology such as Code of Federal Regulations (CFR), Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) Guidance Documents, in European Union (EU) Directives and European Medicines Agency (EMEA) (McPhee and Reimers 2006). For veterinary product registration, Veterinary International Cooperation on Harmonization of technical requirements consists of three associate member regions (Canada, Australia, South Africa and New Zealand) as well as full member regions (Japan, European Union (EU) and the USA). According to the principles and procedure of Good Clinical Practice (GCP), conducting the clinical studies by published the guidelines of VICH. For conducting, recording, designing, monitoring, analyzing, reporting and auditing clinical studies, evaluating veterinary products by the international scientific quality that have to be in Good Clinical Practice (GCP). In the support of product registration, data are submitted in the respect of compliance with the international scientific quality standard that provides the regulators as well as the public, with the assurance of clinical studies integrity. In 2001, VICH GCP guideline is implemented in number nine, GL9; that have a significant challenge to conduct the clinical study for satisfying the conduct clinical study which contains multiple sites spanning several regions of the globe (Mattson and Edwards 42).

In the veterinary clinical study, the monitor will do some and all of the following:

- In investigation selection, done promotion for a sponsor.
- For a consultation, the investigator will be available.
- Investigator and staff have to determine the veterinary clinical study by obtaining the time for study, sufficient study about the animal and capability of the study site.
- Requirements of study material are confirmed by the study staff.
- Investigator accepts the responsibility for understanding and conducts the study: studies protocol's nature and details, studies of animals are appropriate to control the human care, the status of Investigational Veterinary Product (IVP) and with IVP and control product,

restrictions and controls on food-producing animals.

- In clinical studies, followed the requirements of sponsor work, GCP, to ensure the study protocol by visiting the investigator with sufficient frequency and requirements of applicable requirements.
- The collection of the data process and the result of the study should not be bias in any manner.
- Recorded and obtained the animal-related information by the consent of animal owner or agent.
- Confirm that all the recorded data are correctly or completely.
- To confirm that missing, illegible or corrected documented are fully explained.
- To confirm that management documents from control products and IVP.
- Study communications are provided by the recorded details and accurate data.
- At the end of the study, the report's summary is provided at the appropriate intervals of the activities to the sponsor (McPhee and Reimers 2006).

Laboratory Selection

In clinical studies, use the range of laboratories that is varied from the standard diagnostic laboratories to unique specialist university facilities. The basic requirements of the laboratory are carried out by the sponsor the organization and control the investigator by the sub-contracted to a Contract Research Organization (CRO) or institution. Verifiable evidence is obtained by qualified staff whose are educated, expertise and training that are available by required study and performed the tasks. The requirements of the study and GCP which is taken by the understood analytical staff and it also requirements of study prior to involvement in the laboratory study. Before the analysis of any evidence, requirements of appropriate resources and facilities, equipment are calibrated and certified and follow procedure according to the equipment. According to International Organization for Standardization (ISO), standards published the submission with or accreditation to GCP, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) quality systems and using the accredited staff to specialty bodies such as the degree of Veterinary Surgeons form Royal College in the UK. The confidence of laboratory monitor is required in laboratory's requirement but in case of lack of confidence, it's should be reported to the sponsor and supported to evidence and laboratory evidence are dirty and untidy. Cover the requirements of the laboratory by laboratory monitor with the senior laboratory staff, they include:

- Quality Assurance (QA) audits and monitor visits facility.
- Standards and Quality
- Standard Operating Procedures and protocol requirements.
- Requirements of types of reporting such as direct reporting of results and an analytical report.
- Timelines and quality receive the delivery
- On progress, changes, problems etc., do the provision of communications
- Confidentiality
- Method validation and/or transfer
- Payments
- Records have storage and retention (McPhee and Reimers 2006)

With other diagnostic procedures, laboratory tests should be used but before following these laboratory test, two diagnostic procedures are imperative:

- A complete history should be obtained
- Physical examination should be performed

Diagnostician can select the diagnostic procedure by gaining the knowledge from performing this two procedure which clarifies or classify the problems. In domestic mammals, Veterinarians commonly use the laboratory system with other procedures that classify and clarify the pathologic states. Somebody systems (Nervous, cardiovascular, integuments and skeletal) are estimated by using the visual or imaging methods (radiography, ultrasonography, and physical examination) while other body systems (urinary,

endocrine and hemic) are estimated by laboratory tests.

Body fluids (serum, blood, cerebrospinal fluid, peritoneal fluid, urine, pleural fluid and synovia), tissue samples or feces of veterinary are analysis by many laboratory tests or assays. Procedures of clinical laboratory fall into one of the three large groups, which is as follows:

- Clinical hematology assays: On whole body samples, tests are fully completed.
- Clinical chemistry assays: On serum or plasma samples, tests are fully completed.
- Clinical microscopy: it contains four types of microscopy which are clinical cytology, clinical parasitology, urine sediment analysis and surgical histopathology (Stockham and Scott 2008).

Quality Assurance

By implementing the quality audit procedure, confirm the quality and integrity of data from clinical studies which should be well-recognized and accepted quality assurance with its principles that is the statement of VICH GL9 (McPhee and Reimers 2006). Pharmacovigilance system contains the processes to monitor the performance and effectiveness of clinical veterinary and it includes the following factors of the quality system:

- By its responsible, contain the reviews of quality systems for management
- Inspections
- Audits
- Compliance monitoring
- With medicinal products, evaluate the effective actions which contain the minimum risks and supporting their safe and use in patients (https://www.sfda.gov.sa).

Some concepts are included in the quality assurance, which is as follows:

- Because of a variety of analytical factors (such as pipetting errors, electronic interference, reagent deterioration and incubation errors), every laboratory tests produce the erroneous results. These errors are to be detected by the analysis of samples that should have a quality assurance program and provide the result without the erroneous.
- Some random analytical error occurred in each laboratory tests but in manual assays have more random errors in which includes automated methods because people cannot reproduce their work as well as a machine can.
- Acceptance random error for a clinical assay in quality assurance programs that is another concept which is based on changes in biologically significant in the result. Particular analyte have biologic variations in case of within individual and between an individual that are small and made the clinical decisions when in a test of the laboratory, have a minor change in the result and random error is relatively small (Stockham and Scott 2008).

Review of Literature

Hansen 2003, dictated that by frequent analysis of objectively coded behaviors, accomplished the pain behavior in an animal that is evaluated. Provided the opportunities for pet dogs in a veterinary hospital for clinical research such as surgeries otherwise unavailable of these opportunities, obtain the difficulties. By performing the treatment on client-owned pets in private practice environment, hope so that result was obtained in better application to clinical and laboratory animal husbandry. Understanding increase by the positive result is obtained from their client pets and this understanding on moderately painful abdominal surgery that is the impact of two different analgesic protocols.

Kerby 2015, in this paper, explain the case study due to which understand the types of data in veterinary medicine as well as provides the clues that how to managed and shared the data. On the base of this knowledge, developing more data services and speak more knowledgeable data about their need by the subject-specialist librarians. This paper concluded that improving and established the methods of managing and recording the data. It also provides the improving data storage options, best practice to manage the data and it gave the top priorities of sharing the data. For a good data management

system, subject-specialist librarians should be educated in veterinary medicine study.

Ducrot *et al.* 2016, stated that it is important that livestock of animals contain the infectious diseases which are a rapid shift in geographical poles. Research shows a rapid adaptation to emerging subjects by the evolution of the topics. This paper concluded that the interpreted in the potent view and universal driver which influence the topic selection process such as financial incentives which are available by funding agencies. During the 2006-2013 period, increasing the 13% annual growth rate in the respect of influenza that is direct consequence made to promote several studies that including H5N1 and H1N1 epidemics.

Page *et al.* 2016, stated that by veterinarians, pet-owning public and scientist, continuing to encourage to improve the clinical trials by doing the research and education. Translational research knowledge was obtained by the biomedical researchers whose are identifies the diseases in companion animals and have the various opportunities and resources to do so. During conducting the analysis, specialists of veterinary should be aware of precautions through our practices. For patients and owners, veterinary practitioners should need to be educated in clinical trials. Every owner of practitioners understands of their knowledge by the enrollment in clinical trials that help in future via applying on human and animals.

Davies *et al.* 2017, on behalf of animal, comparative and translational science that is environmental and human health is not linear and unidirectional. In regulated and non-regulated research, require the constant scrutiny as new data that is necessary for all new ongoing work. The term mutual dependency means that scientist performs the research on a shared vision of rigor and this research gives the outcomes in minimizing the risk of inconsistent data quality and irreproducible.

Oyama, Ellenberg and Shaw 2017, in veterinary medicine, the age of prospective Randomized Clinical Trials (RCT) is fully upon us. To confirm the valid design and accurate reporting of RCT and maximal leverage, by the need for veterinary medicine. Also needed to the attention in issues of planning, reporting, different forms of risk analysis and study endpoints. In veterinary and human medicine, drawn the insights from greater cooperation between biostatisticians and wealth of experience with RCTs in the human medical field and achieving the useful results by performing the trials. For improvement of a clinical study, increasing the training of veterinary students, specialist, and generalists.

Conclusion

Clinical study plays an important role in veterinary medicine because of infectious animal are treated with the proper arrangement of the laboratory such as proper managed the instruments, data are properly stored in the storage area etc. Veterinary scientists are fully educated and trained from the high level of the university such as the Royal University of Veterinary Medicine. It's also continually encourage to improve the clinical studies by which treatment should be provided in a better manner. During the analysis, the veterinary specialist should be aware of research opportunities and how to integrate them into their practices.

References:

Davies, R., et al. "Quality Assurance and Best Research Practices for Non-Regulated Veterinary Clinical Studies." *BMC Veterinary Research*, vol. 13, no. 1, 2017, doi: 10.1186/s12917-017-1153-x.

Ducrot, Christian, et al. "Scientific Literature on Infectious Diseases Affecting Livestock Animals, Longitudinal Worldwide Bibliometric Analysis." *Veterinary Research*, vol. 47, no. 1, 2016, doi: 10.1186/s13567-015-0280-2.

Guideline on Good Pharmacovigilance Practices (GVP). Saudi Food and Drug Authority, www.sfda.gov.sa/en/drug/drug_reg/Regulations/Guideline on Good Pharmacovigilance (GVP).pdf.

Hansen, B. D. "Assessment of Pain in Dogs: Veterinary Clinical Studies." *ILAR Journal*, vol. 44, no. 3, Jan. 2003, pp. 197–205., doi:10.1093/ilar.44.3.197.

Kerby, Erin. "Research Data Practices in Veterinary Medicine: A Case Study." *Journal of EScience Librarianship*, vol. 4, no. 1, 2015, doi:10.7191/jeslib.2015.1073.

Mattson, Donna, and Lindsey Edwards. "Veterinary Clinical Studies: Managing Expectations." *International Animal Health Journal*, vol. 2, no. 1, pp. 42–48.

Mcphee, Iain, and Monte Reimers. "The Role of the Monitor in Veterinary Clinical Studies." *The Quality Assurance Journal*, vol. 10, no. 3, 2006, pp. 159–181., doi:10.1002/qaj.376.

Oyama, M.a., et al. "Clinical Trials in Veterinary Medicine: A New Era Brings New Challenges." *Journal of Veterinary Internal Medicine*, vol. 31, no. 4, 2017, pp. 970–978., doi:10.1111/jvim.14744.

Page, R., et al. "Conduct, Oversight, and Ethical Considerations of Clinical Trials in Companion Animals with Cancer: Report of a Workshop on Best Practice Recommendations." *Journal of Veterinary Internal Medicine*, vol. 30, no. 2, 2016, pp. 527–535., doi:10.1111/jvim.13916.

Rosenfeld, Andrew J., and Sharon M. Dial. *Clinical Pathology for the Veterinary Team*. Wiley-Blackwell, 2011.

Stockham, Steven L., and Michael A. Scott. *Fundamentals of Veterinary Clinical Pathology*. Wiley-Blackwell, 2008.