Professional Master's Degree
Veterinary Clinical Trials

tech technological university

tech technological university

Professional Master's Degree
Veterinary Clinical Trials

- Modality: **online**
- Duration: **12 months**
- Certificate: **TECH Technological University**
- Dedication: **16h/week**
- Schedule: **at your own pace**
- Exams: **online**

Website: **www.techtitute.com/us/veterinary-medicine/professional-master-degree/master-veterinary-clinical-trials**

Index

01 Introduction p. 4

02 Objectives p. 8

03 Skills p. 14

04 Course Management p. 18

05 Structure and Content p. 24

06 Methodology p. 42

07 Certificate p. 50

01

Introduction

Veterinary clinical trials are essential to ensure the effectiveness of medication or substances, as well as their safety in the target species. This is an area that has undergone a variety of changes over time as a result of increased social awareness surrounding the subject of animal welfare. Based on this, professionals in this field must have a detailed understanding of the current regulations applied to this area, since they are the ones who ensure compliance with them. In order to help students keep up to date, TECH has developed a program that will enable further learning of the latest developments in clinical trials, their epidemiology and innovative approach strategies applicable to both laboratories and farms. Thanks to this 100% online, comprehensive 1,500-hour course, students will be able to perfect their skills in veterinary research and control.

The best program on the current academic market to bring you up to date on the latest developments in veterinary clinical trials, all 100% online and in only 12 months of theoretical-practical academic experience"

The veterinarian's role as part of a multidisciplinary team to develop new treatments applicable to humans and animals is fundamental and has taken on special relevance in recent years. Thanks to the development of clinical trials, it is now possible to have increasingly safe, effective and specialized medication for each pathology. This way, an experimental evaluation is carried out on the target species or a particular category, in order to guarantee its safety once it becomes available on the market.

The importance of developing this practice in an appropriate environment and with conditions that guarantee compliance with animal welfare regulations, as well as on the basis of current legislation, relies on veterinary professional's involvement. For this reason, TECH has developed a complete program with which students will be able, to get up to date on the latest developments in this field, in just 12 months.

It is a program designed by experts in the field with years of experience in research project management. Thanks to their participation, it has been possible to create a new and thorough syllabus with which specialists will be able to update their knowledge in: epidemiology applied to veterinary clinical trials and its approach, the design and methodology of the processes in laboratories and farms, and the current regulations.

Students will have 1,500 hours of the best theoretical, practical and additional content, the latter presented in different formats: detailed videos, research articles, complementary reading material and much more! Everything you need to delve in a personalized way in the different sections of the program, which will be available 100% online. You will be able to improve your veterinary skills through an academic experience adapted to your needs and those of today's industry

This **Professional Master's Degree in Veterinary Clinical Trials** contains the most complete and up-to-date scientific program on the market. The most important features of the program include:

- The development of case studies presented by experts in Veterinary Medicine
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- Practical exercises where self-assessment can be used to improve learning
- Its special emphasis on innovative methodologies
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- Content that is accessible from any fixed or portable device with an Internet connection

A program designed to help professionals achieve excellence in the veterinary research environment through 1,500 hours of the best academic material"

You will work with the most comprehensive and cutting-edge information related to clinical research applied to veterinary trials in farms and laboratories"

All content will be available on the Virtual Campus from the beginning of the course and 100% online In addition, it can be downloaded to any device with internet connection.

A program where you will be able to perfect your skills in the analysis of veterinary genetic epidemiology and in the preventive and curative treatment of the most common diseases.

The program's teaching staff includes professionals from the sector who contribute their work experience to this training program, as well as renowned specialists from leading societies and prestigious universities.

The multimedia content, developed with the latest educational technology, will provide the professional with situated and contextual learning, i.e., a simulated environment that will provide immersive education programmed to learn in real situations.

This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise during the academic year. For this purpose, the student will be assisted by an innovative interactive video system created by renowned and experienced experts.

02

Objectives

The objective of this course is none other than to provide students with all the academic tools that will enable them to achieve their own goals in their professional sector. TECH and its team of experts have invested dozens of hours in creating a complete, up-to-date, comprehensive and top-quality qualification, adapted to the most demanding market specifications. Therefore, by passing the course, students will have acquired all the necessary skills to perform successfully, all on the basis of the latest information related to veterinary clinical trials.

If your objectives include mastering the evaluation process in the veterinary scientific and clinical method, enroll in this Professional Master's Degree because it will be perfect for you"

General Objectives

- Generate specialized knowledge in the design and interpretation of a clinical trial
- Examine the key features of clinical trials
- Analyze key analytical concepts in clinical trials
- Justify decisions made to solve problems
- Evaluate behavioral aspects and standardized procedures of clinical trials
- Review legislation on analytical, toxico-pharmacological and clinical standards and protocols for veterinary drug testing
- Assess the regulatory environment in relation to clinical trials
- Develop standards for veterinary clinical trials
- Generate specialized knowledge to carry out clinical research
- Establish the correct methodology for conducting veterinary clinical trials
- Develop advanced knowledge for the development of a protocol for the conduct of a clinical trial with veterinary drugs
- Analyze the structure of the different regulatory agencies and organizations and their attributions
- Correctly manage the documentation generated in the framework of the application, follow-up and completion of a veterinary clinical trial

A unique academic opportunity to delve into the comprehensive management of PubMed and MESH and advanced information and content searching for veterinary research"

Specific Objectives

Module 1. Clinical Research and Clinical Trials Evidence-based veterinary medicine (EBVM)

- Generate a good clinical research question
- Plan an efficient, effective, and ethical design
- Demonstrate that a clinical trial is feasible, efficient, cost-effective and easy to implement
- Minimize errors (systematic and randomized) that may threaten the conclusions of a clinical trial
- Generate specialized knowledge in clinical performance according to Evidence-Based Medicine
- Encourage the search for scientific information, store it, evaluate it and use it through the use of computer applications
- Critically evaluate how a scientific paper is reviewed
- Synthesize ideas and analyze information in a critical, evaluative and analytical manner

Module 2. Applied Epidemiology in Veterinary Clinical Trials

- Develop autonomy to participate in research projects and scientific collaborations in the field of clinical trials and in interdisciplinary contexts
- Examine the different databases, their validation and the different tools for data management in clinical trials
- Apply problem solving techniques in the creation and development of clinical trials under the scientific method and new environments
- Properly elaborate structured projects focused on clinical and epidemiological trial activity
- Generate the integration of knowledge to face the formulation of judgments and conclusions generated in the studies
- Analyze the processes that allow the introduction of new veterinary medication in the market, as well as to incorporate the ethical principles involved

Module 3. Approach to Veterinary Clinical Trials in Different Veterinary Settings Laboratories and Farms

- Examine, step by step, quality assurance and best practices in the application and production of vaccines
- Develop good clinical practices to regulate personnel and aspects involved in studies
- Manage field trials, demonstrate safety and efficacy in terms of environmental conditions, care and possible adverse reactions
- Properly elaborate tests in different areas and give solidity to the sampling method
- Apply different recommendations to assess exposure to different pathogens and collect quantitative information in order to develop study and work patterns
- Analyze the processes that can lead to the emergence of resistance to antimicrobial agents and know how to collect therapeutic information to produce results

Module 4. Veterinary Clinical Trial I. Design and Methodology

- Establish the correct lines and procedures to develop clinical research to evaluate the efficacy and safety of veterinary medication
- Determine research environments and competent personnel
- Examine the practices of clinical trials
- Develop necessary technical documentation
- Analyze relations with regulatory agencies

Module 5. Veterinary Clinical Trials II. Trial Treatment

- Choose the right type of veterinary clinical trial for each study
- Establish appropriate criteria for the study population
- Analyze the main problems that can arise in methodological approaches to treatment in the trial
- Examine the Monitoring Treatment Plan in the Trial
- Specify data conditions, data handling, processing, and corrections
- Generate specialized knowledge to carry out specialized methodology in clinical research regarding treatment in clinical trials in Veterinary Oncology, Veterinary Infectious Pathology and Veterinary Neurology

Module 6. Genetic diseases in Veterinary Clinical Trials (VCT). Veterinary Genetic Epidemiology

- Determine groups of individuals and examine population parameters useful in genetic epidemiology studies
- Analyze the factors and elements in the epidemiological triad
- Demonstrate the contribution of triad factors to genetic disease to expose and justify their applicability to epidemiological studies
- Establish agent-disease causality relationships
- Analyze data and recognize and control sources of bias to differentiate between studies
- Compile data and generate incidence and prevalence measures from raw data
- Formalize disease-exposure association tests
- Present, propose and implement different appropriate designs in relation to observational data

Module 7. Principal Investigators, Sponsors and Monitors of Veterinary Clinical Trials (VCTs)

- Determine the role of each participant in the veterinary clinical trial research process, both in general and of the veterinarian in particular
- Establish different roles in the research process and control of results
- Examine factors and elements of the skills of actors in the testing process
- Analyze the actions that guide the clinical trial process
- Manage projects and clinical trials in scientific, technical and monitoring contexts
- Determine the role and interests of the different stakeholders required
- Analyze recruitment strategies for companies and researchers
- Audit the research process and detect events of relevance to the progress of the research process
- Issue partial, event and final reports
- Decide on study sites and their monitoring
- Guarantee data quality controls
- Manage applicable legislation

Module 8. Pharmacovigilance and Pharmacoeconomics

- Examine the overview of the European regulatory framework contained in Volume 9B of Eudralex (Pharmacovigilance for Medicinal Products for Veterinary Use)
- Determine the responsibilities of the monitor within the pharmacovigilance system (DDPS) and the responsibilities of the Qualified Person for Pharmaco Vigilance (QPPV)
- Correctly analyze and present safety reviews of veterinary products
- Determine the importance of health economics through the economic medicine evaluation
- Design and perform cost-benefit, cost-effectiveness, cost-utility and cost-minimization analyses Uncover potentially hidden costs: hospitalization days, concomitant medication, treatment of adverse effects, complementary tests, etc

Module 9. Legislation Applicable to Veterinary Clinical Trials

- Comparatively assess the legislation on clinical trials with that of other European countries
- Establish the structure of European (EMA) regulatory agencies

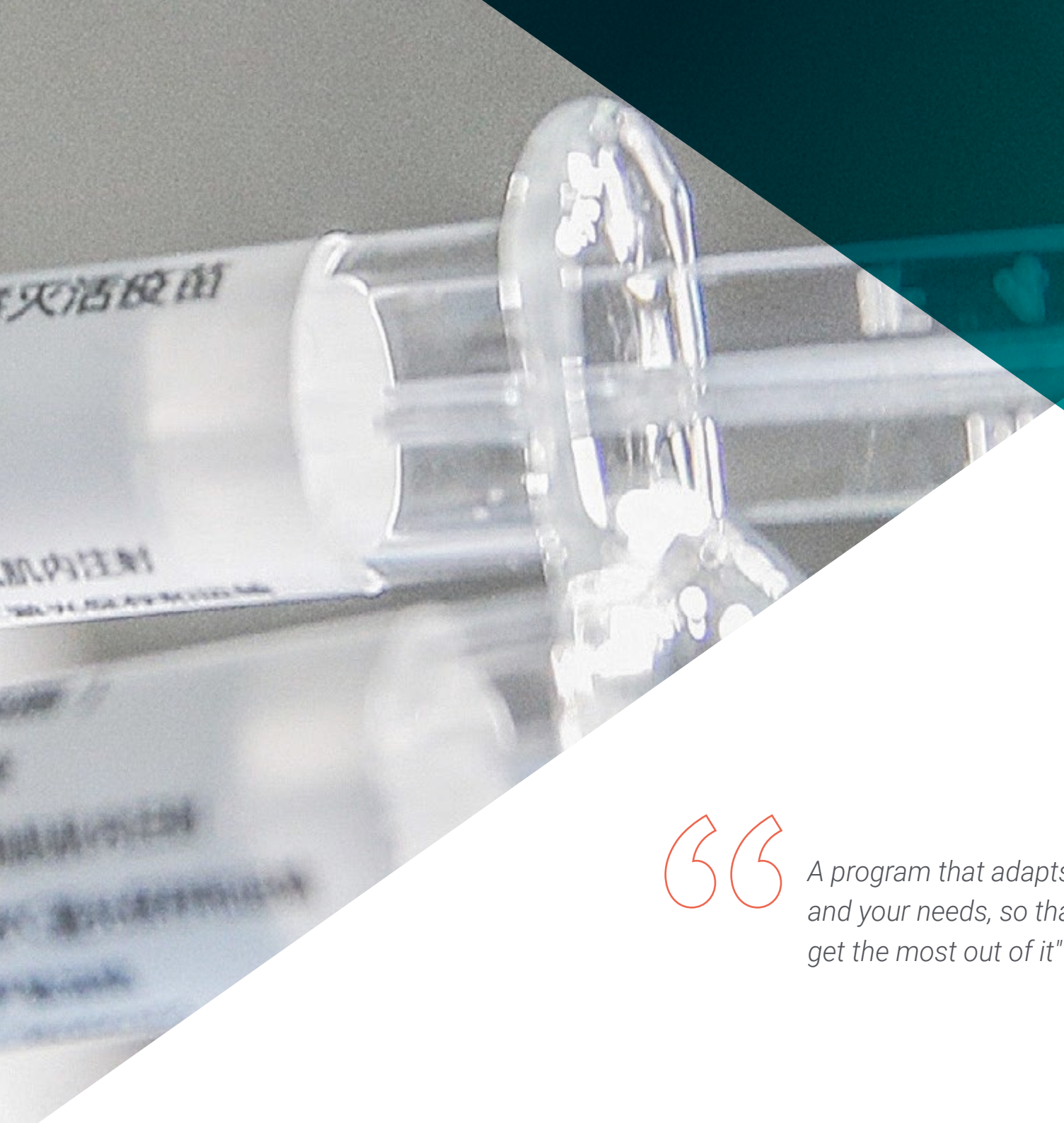
Module 10. Veterinary Clinical Trials II. Management, Start-ups and Commissioning

- Analyze the structure of the safety and efficacy section of a regulatory dossier
- Follow international guidelines on the conduct of veterinary safety studies (Target Animal Safety)
- Establish the importance of quality in data generation and the use of auditing as a method of quality assurance
- Determine how to select the right laboratory for the analysis of biological samples of trail frameworks
- Generate specialized knowledge to assign, organize and prioritize the tasks, roles and responsibilities of trial participants
- Perform adequate document management for subsequent submission to the corresponding regulatory agencies for evaluation
- Analyze and correctly present the results of a clinical trial in scientific articles following international standards

03

Skills

TECH always designs each of its programs thinking about what is best for the professionals who will access it. Thanks to this, it is possible to create highly beneficial academic experiences for the improvement of their professional skills based on the exhaustive updating of their knowledge and the resolution of practical cases of real situations In addition, it includes a multitude of extra material with which students can further their knowledge, a personalized way, in the different sections, according to their level of demand and interest.



A program that adapts to you, your requirements and your needs, so that you are guaranteed to get the most out of it"

General Skills

- Analyze clinical cases objectively and precisely
- Evaluate behavioral aspects and standardized procedures of clinical trials
- Establish the correct guidelines and procedures for clinical research development

You will have access to clinical cases based on real and frequent situations in the veterinary research environment, so that you can put into practice and perfect your problem-solving skills"

Specific Skills

- Analyze key analytical concepts in clinical trials
- Develop standards for veterinary clinical trials
- Generate specialized knowledge to carry out clinical research
- Plan and organize all entities involved in a regulatory clinical trial
- Determine treatment response assessment methods
- Develop specialized knowledge to correctly interpret epidemiology results and reports with ethical responsibility and based on the knowledge acquired
- Identify main causes of the diseases
- Identify sources of information and analyze data using appropriate statistical procedures
- Develop advanced knowledge in the biology and management of animals and their interaction with the environment, taking into account the individuality of each species
- Establish activities of the Clinical Study Monitor according to those proposed by the International Conference on Harmonization of Requirements
- Examine an important element in the clinical research process such as data and data management
- Perform a correct benefit-risk assessment of medication under review

04

Course Management

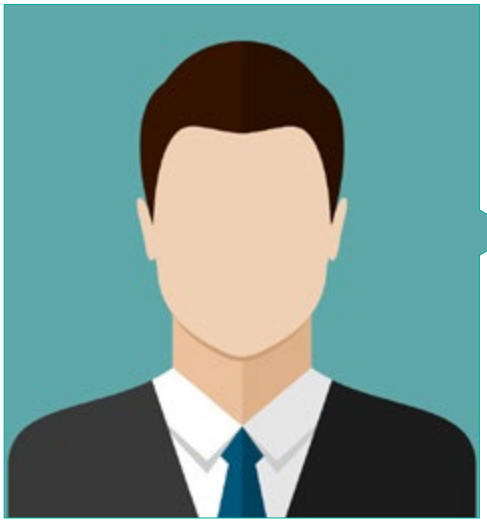
Not all universities include teaching support formed by specialized teams in the area in their programs, in which the degree is developed, in this case on Veterinary Medicine However, TECH does In addition, this university submits candidates to an exhaustive and demanding analysis, resulting in the formation of the best faculty, made up of experts with broad and extensive professional careers in the sector Therefore, specialists who take this Professional Master's Degree will have their support and will be able to implement the most innovative and effective clinical strategies in their practice

You will be able to resolve any doubts you may have through direct consultation with the teaching staff, who will be at your disposal throughout the program"

Management

Dr. Martín Palomino, Pedro

- PhD in Veterinary Medicine from the University of Extremadura
- Diploma in Public Health from the National School of Health (ENS), Instituto de Salud Carlos III (ISCIII)
- Master's Degree in Veterinary Medicine from the Faculty of Veterinary Medicine in Murcia
- Director of Thesis Projects
- Part-time contract professor at the Universidad Alfonso X El Sabio, Subjects: Infectious Diseases, Zoonoses and Public Health



Dr. Fernández García, José Luis

- PhD in Veterinary Medicine from the University of Extremadura
- Graduate in Veterinary Medicine with degree from the University of Extremadura
- Master's Degree in Biotechnology from the CNB Severo Ochoa
- Professor of Animal Production at the University of Extremadura, Spain

Teachers

Dr. González, José Antonio

- Clinical veterinarian for small animals since 2002
- Graduate in Veterinary Medicine from the University of Cáceres, specializing in Animal Medicine and Health and Bromatology, Health and Food Technology
- Clinical practice professor and tutor for students and assistants
- Professor in specialized education centers

Ms. Ripa López - Barrantes, Adriana

- Collaborating inspector of the Animal Protection Area of the Community of Madrid
- Practical area of small animals in several clinics in Madrid
- Graduate in Veterinary Medicine from the Universidad Alfonso X el Sabio
- Master's Degree in Veterinary Science Research from the Complutense University
- Master's Degree in Teacher Training at the University of La Rioja
- Professor at the Alfonso X el Sabio University: Infectious Diseases, Zoonoses and Epidemiology

Dr. Sánchez Sánchez de Rojas, Leyre

- Acting Officer in the area of efficiency of Pharmacological Veterinary Medicines in the Spanish Agency of Medicines and Health Products
- Coordinator and manager of clinical trials in the Neurosurgery Department of the Hospital Clínico San Carlos
- Doctor in Biomedical Research from the Complutense University of Madrid
- Graduate in Veterinary Medicine from the Alfonso X El Sabio University
- Official Master's Degree in Veterinary Science Research at the Complutense University of Madrid
- Master's Degree in Integral Management of Veterinary Clinical Trials by Universidad Europea

Dr. Cortés Gamundi, Iván

- PVSO Transition Associate at Novartis
- Graduate in Microbiology from the Autonomous University of Barcelona
- Master's Degree in Pharmacology from the Autonomous University of Barcelona

Dr. Espigares Espigares, David

- Head of Swine Technical Service at Ceva Salud Animal
- Secretary of AVEPOMUR (Association of Swine Veterinarians of the Region of Murcia)
- Graduate in Veterinary Medicine in the University of Murcia
- Master's Degree in Pharmaceutical Marketing from UNED/Cesif
- Master's Degree in Integral Management of in Veterinary Clinical Trials by Universidad Europea of Madrid
- Specialization stays at the University of Montreal (Canada) and at GD Deventer (The Netherlands)
- Collaborator of Master's Degree in Swine Health and Production (University of Madrid, Zaragoza and Lleida

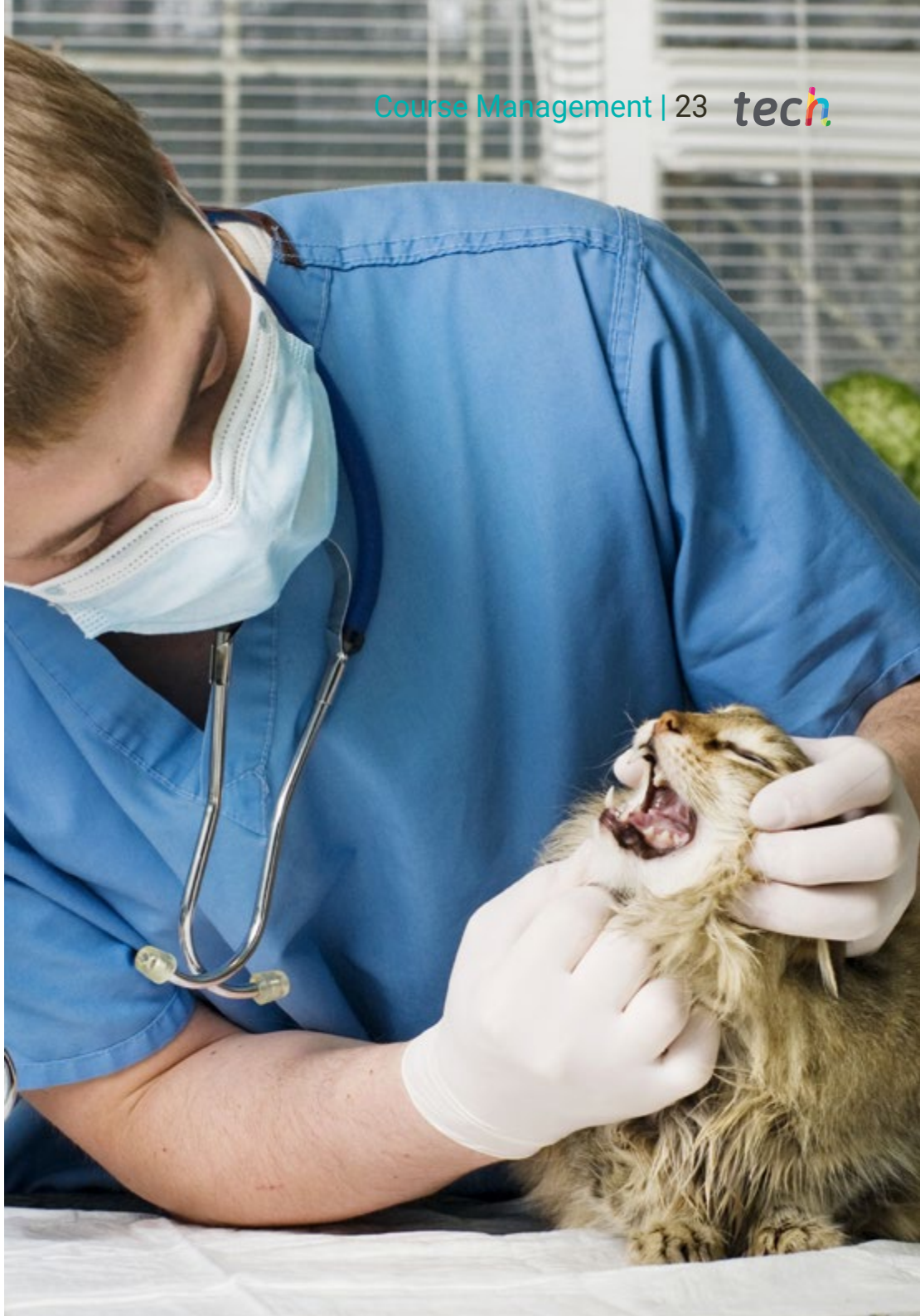
Dr. García Castro, Javier

- Positions: Head of the Cellular Biotechnology Unit at the Instituto de Salud Carlos III
- Senior Professor at the Universidad Alfonso X el Sabio
- Area Director of the Andalusia Stem Cell Bank
- Researcher at Hospital Universitario Niño Jesús
- Guest lecturer in numerous Master's Degree programs at prestigious universities
- PhD in Biological Sciences and Master's Degree in Administration and Management of Biotechnology Companies

Dr. Aguilera Martínez, Ángel

- Positions: Doctorate in Veterinary Medicine, Universidad Complutense de Madrid
- Degree in Veterinary Medicine. Complutense University of Madrid
- Master's Degree in Environmental Management (Universidad Las Palmas de Gran Canaria)
- Postgraduate specialist in Microbiology and Epizootiology. General Manager of Education. Ministor of Defense
- Microbiology, Hygiene and Sanitation Specialist
- ACAP: Assistant Doctor Professor Universidad Alfonso X el Sabio
- ACAP: Collaborating Professor Alfonso X el Sabio University
- Defense Military Veterinary Center
- Subjects Taught: Microbiology, Infectious Diseases, Epidemiology, Zoonoses and Public Health
- Hospital Militar Central Universitario de la Defensa "GÓMEZ ULLA" (1990-1996). Experimental Medicine and Surgery Service
- Associate Professor of Epidemiology and Infectious Diseases Alfonso X el Sabio University

An impressive teaching staff, made up of specialists from different areas of expertise will be your teachers during your training: a unique opportunity not to be missed"



05

Structure and Content

TECH uses the best academic tools and the effective and innovative Relearning methodology in all of its programs In addition, it guarantees a series of minimum hours of additional material in different formats, so that students can not only contextualize the information developed in the syllabus, but also deepen in those aspects they consider more interesting or relevant for their work performance. All this is what makes programs like this one the best in the market, thanks to these, veterinarians will be able to develop extensively and conscientiously, contributing to improve their professional future through a 100% online program.

Thanks to the Relearning methodology, you will not have to invest extra hours studying the program, as you will see a natural and progressive updating of your knowledge"

Module 1. Clinical Research and Trials. Evidence-Based veterinary medicine (EBVM)

1.1. Evolution of Clinical Research: Historical Aspects
- 1.1.1. Pre-James Lind Era
- 1.1.2. James Lind and Scurvy Trial
- 1.1.3. Arrival of Placebo
- 1.1.4. First Double-Blind Controlled Trial
- 1.1.5. First Randomized Curative Trial: Streptomycin Randomized Trial

1.2. Research. The Scientific Method
- 1.2.1. Research
  - 1.2.1.1. Necessary Conditions for Conducting Research
  - 1.2.1.2. Research Methodology
  - 1.2.1.3. Research Memory
- 1.2.2. The Scientific Method
  - 1.2.2.1. Concept
  - 1.2.2.2. Objectives of the Scientific Method
  - 1.2.2.3. Characteristics of the Scientific Method
  - 1.2.2.4. Budgets of the Scientific Method
  - 1.2.2.5. Techniques of the Scientific Method
  - 1.2.2.6. Stages of the Scientific Method
- 1.2.3. Summary

1.3. Clinical Research
- 1.3.1. The Anatomy and Physiology of Clinical Research
- 1.3.2. Anatomy of Clinical Research: What Does It Involve?
  - 1.3.2.1. Research Question
  - 1.3.2.2. Background and Significance
  - 1.3.2.3. Design
  - 1.3.2.4. Study Subjects
  - 1.3.2.5. Variables
  - 1.3.2.6. Statistics
- 1.3.3. Research Physiology: What Does It Involve?
  - 1.3.3.1. Study Design
    - 1.3.3.1.1. Study Protocols
    - 1.3.3.1.2. Compensation
  - 1.3.3.2. Implement Studies
  - 1.3.3.3. Causal Inference
  - 1.3.3.4. Research Errors
    - 1.3.3.4.1. Random Error
    - 1.3.3.4.2. Systematic Error
- 1.3.4. Summary

1.4. Research Question
- 1.4.1. Origins of Research Questions
  - 1.4.1.1. Research Question in Literature
  - 1.4.1.2. New Ideas and Techniques
  - 1.4.1.3. Choosing a Mentor
- 1.4.2. Good Research Question Characteristics
  - 1.4.2.1. Feasible
    - 1.4.2.1.1. Number of Individuals
    - 1.4.2.1.2. Technical Expertise
    - 1.4.2.1.3. Time and Cost
  - 1.4.2.2. Interested Parties
  - 1.4.2.3. Originality
  - 1.4.2.4. Relevance
- 1.4.3. Research Question Development and Study Plan
  - 1.4.3.1. Problems and Solutions
  - 1.4.3.2. Primary and Secondary Questions
- 1.4.4. Translational Research
  - 1.4.4.1. Translation of Research from Clinical Trials to Populations
- 1.4.5. Summary

1.5. Sample Size Calculation
- 1.5.1. Hypotheses
- 1.5.2. Hypotheses Types
  - 1.5.2.1. Null and Alternative Hypothesis
  - 1.5.2.2. One-Sided and Two-Sided Alternative Hypotheses
- 1.5.3. Statistical Principles
  - 1.5.3.1. Type I and II Errors
  - 1.5.3.2. Effect Size
  - 1.5.3.3. Alpha (α) and Beta (β)
  - 1.5.3.4. Probability Value (p)
  - 1.5.3.5. Types of Statistical Tests
- 1.5.4. Additional Concepts
  - 1.5.4.1. Variability
  - 1.5.4.2. Multiple and Post Hoc Hypotheses
  - 1.5.4.3. Primary and Secondary Hypotheses
- 1.5.5. Summary

1.6. Bibliographic Search: Access to Scientific Information
- 1.6.1. What is Scientific Information: How Is It Presented?
- 1.6.2. What Do We Need It For and What Should We Do With It?
- 1.6.3. Types of Questions
- 1.6.4. Preparing for the Search: Before, During and After
- 1.6.5. Where to Look Data Bases
- 1.6.6. What Do We Need to Consult Databases? Interrogation Languages and Keywords
- 1.6.7. Thesauri in Health Sciences
- 1.6.8. PubMed
  - 1.6.8.1. Introduction
  - 1.6.8.2. Simple Search. MESH Descriptors. Advanced Search
  - 1.6.8.3. Filters
  - 1.6.8.4. Results
- 1.6.9. Where and How to Locate Evidence
  - 1.6.9.1. Introduction
  - 1.6.9.2. Pyramids of Evidence and Information Sources

1.6.10. Up to Date
1.6.11. PubMed Clinical Queries
1.6.12. Evidence-Based Medicine Databases
1.6.13. How to Select, Read and Use Information
1.6.13.1. Introduction
1.6.13.2. What Does Critical Reading Look Like?
1.6.13.3. Types of Scientific Articles
1.6.13.4. How to Select and Read Information
1.6.13.5. Critical Reading and Checklists
1.6.13.6. Using Information Bibliography Managers
1.6.13.7. How to Create a Bibliography
1.6.14. Summary
1.7. Evidence-Based Veterinary Medicine (EBVM)
1.7.1. What is Evidence-Based Veterinary Medicine?
1.7.1.1. Evidence-Based Veterinary Medicine through History
1.7.1.2. Why is Evidence-Based Veterinary Medicine Important?
1.7.1.2.1. Clinical Applications
1.7.1.3. Comparison of Traditional Methods and EBVM
1.7.1.4. How Do I Start
1.7.1.5. Challenges of Evidence-Based Veterinary Medicine
1.7.2. Information Sources
1.7.2.1. Introduction
1.7.2.2. Background and Prior Knowledge
1.7.2.3. Evidence Hierarchy
1.7.2.4. Traditional Information Resources
1.7.2.4.1. Magazines
1.7.2.4.2. Textbooks and Other Publications
1.7.2.4.3. Personal Experience
1.7.3. Internet
1.7.4. Veterinary Information Resources on the Internet
1.7.4.1. CABdirec
1.7.4.2. Consultant
1.7.4.3. Inno-vet
1.7.4.4. International Veterinary Information Service
1.7.4.5. Medline/Pubmed
1.7.5. Research Studies
1.7.5.1. Hierarchy of Evidence and Experimental Design
1.7.5.2. Research Methods Guide
1.7.5.3. Experimental Studies
1.7.5.3.1. Randomized Controlled Tests
1.7.5.3.2. Cross-Sectional Designs
1.7.5.4. Observational Study
1.7.5.4.1. Cohort Studies
1.7.5.4.2. Cross-Sectional Survey
1.7.5.4.3. Case Control Studies
1.7.5.5. Descriptive Studies
1.7.6. Assessing the Evidence
1.7.6.1. Introductory Concepts
1.7.6.2. Probability and Likelihood
1.7.6.3. Risk and Uncertainty
1.7.6.4. The Importance of Statistics
1.7.7. Evidence in Veterinary Education
1.7.7.1. Evidence-Based Veterinary Tools
1.7.7.2. Finding What Is and Isn't in Literature
1.7.7.3. Necessary Resources for Veterinary Evidence-based Practice
1.7.7.4. Clinical Audit in Veterinary Practice
1.7.7.4.1. What Is Clinical Audit?
1.7.7.4.2. Why Do We Need an Audit?
1.7.7.4.3. How to Perform an Audit
1.7.7.4.4. Clinical Audits in the Future
1.7.8. Summary

1.8. Animal Testing
- 1.8.1. Introduction
- 1.8.2. History
  - 1.8.2.1. Prehistory
  - 1.8.2.2. The Ancient Age
  - 1.8.2.3. The Middle Ages
  - 1.8.2.4. The Renaissance
  - 1.8.2.5. Illustration
  - 1.8.2.6. 19th Century
  - 1.8.2.7. 20th Century
  - 1.8.2.8. 21st Century: The Present
- 1.8.3. Bioethics
  - 1.8.3.1. Introduction to Biological Ethics
  - 1.8.3.2. Position Against Testing
  - 1.8.3.3. Position in Favor of Testing
  - 1.8.3.4. Future Perspectives in Bioethics: Trends

1.9. Animal Ethics
- 1.9.1. Animal Ethics
- 1.9.2. Animal Studies
- 1.9.3. Critical Animal Studies
- 1.9.4. Animal Research
  - 1.9.4.1. Animals in Biomedical and Pharmaceutical Research
    - 1.9.4.1.1. Basic or Preclinical Research
    - 1.9.4.1.2. Clinical Research
    - 1.9.4.1.3. Biotechnology Research
  - 1.9.4.2. Animals in Other Types of Research
    - 1.9.4.2.1. Basic Research.
    - 1.9.4.2.2. Commercial Product Testing
    - 1.9.4.2.3. Military Research
- 1.9.5. Summary

1.10. Laboratory Animals
- 1.10.1. Most Commonly Used Species and Their Special Characteristics
  - 1.10.1.1. Environmental and Management Conditions
  - 1.10.1.2. Experimental Animals Use
- 1.10.2. Ethical Rules
  - 1.10.2.1. International Regulations
    - 1.10.2.1.1. Three Rs Principles
    - 1.10.2.1.2. Declaration Universal of Rights of Animals.
    - 1.10.2.1.3. International Code of Ethics
    - 1.10.2.1.4. Good Laboratory Practices
  - 1.10.2.2. Ethical Regulations in Europe
    - 1.10.2.2.1. Evans Report
    - 1.10.2.2.2. Basel Declaration
- 1.10.3. Legal Regulations
  - 1.10.3.1. Legal Aspects Regulations in Europe

Module 2. Applied Epidemiology in Veterinary Clinical Trials

2.1. Veterinary Epidemiology
- 2.1.1. Historical Background.
- 2.1.2. Epidemiology and Its Uses
- 2.1.3. Causality Criteria
  - 2.1.3.1. Koch's Postulates
  - 2.1.3.2. Bradford Hill Criteria
  - 2.1.3.3. Evans' Postulates
- 2.1.4. Association Types
- 2.1.5. Epidemiological Research
- 2.1.6. Epidemiological Methods
  - 2.1.6.1. Qualitative Epidemiology
  - 2.1.6.2. Quantitative Epidemiology
- 2.1.7. Disease Determinants
  - 2.1.7.1. Factors: Agent, Host, and Environment

2.1.8. Pattern of Disease Progression
2.1.8.1. Transmission, Repertoires, Hosts and Vectors
2.1.8.2. Biological Cycles
2.1.9. Emerging Diseases and Zoonoses
2.2. Epidemiological Data Analysis
2.2.1. Data Collection
2.2.1.1. Epidemiological Surveys
2.2.2. Nature of Data
2.2.3. Databases: Examples of Veterinary Databases and Information Systems
2.2.3.1. Stata Databases
2.2.3.2. SPSS Databases
2.2.4. Types of Variables
2.2.5. Interpretation of Results
2.2.5.1. Pie Charts
2.2.5.2. Bar Chart
2.2.5.3. Histograms
2.2.5.6. Stem and Leaves
2.2.5.7. Cumulative Frequency Polygon
2.2.5.8. Box Chart
2.2.5.9. Scatter Graph
2.2.6. Cartography
2.2.6.1. Geographic Information Systems
2.3. Population Structure
2.3.1. Animal Population Structure
2.3.2. Presentation of a Collective Disease
2.3.2.1. Endemic
2.3.2.2. Epidemic Outbreak
2.3.2.3. Epidemic or Epizootic
2.3.2.4. Pandemic
2.3.2.5. Sporadic

2.3.3. Measurement of Disease in the Population
2.3.3.1. Prevalence
2.3.3.2. Incidence and Cumulative Incidence
2.3.3.3. Incidence Rate or Density
2.3.4. Relationships between the Different Parameters
2.3.4.1. Calculation of the Relationship between Prevalence and Incidence
2.3.5. Rate Adjustment
2.3.6. Measuring Disease Presentation
2.3.6.1. Mortality and Mortality Ratio
2.3.6.2. Morbidity
2.3.6.3. Lethality
2.3.6.4. Survival
2.3.7. Epidemic Curves
2.3.8. Temporal Disease Distribution
2.3.8.1. Single-Source Epidemics
2.3.8.2. Epidemics by Propagation
2.3.8.3. Kendall's Theorem
2.3.9. Evolution of Endemic Situations
2.3.9.1. Time Trends
2.3.9.2. Spatial Disease Distribution

2.4. Epidemiological Research
2.4.1. Study Planning
2.4.2. Types of Epidemiological Studies
2.4.2.1. By Purpose
2.4.2.2. By Sense of Analysis
2.4.2.3. By Time Relationships
2.4.2.4. By Units of Analysis

2.5. Diagnostic Epidemiology
2.5.1. Use of Diagnostic Tests
2.5.2. Diagnostic Concepts
2.5.3. Reliability Assessment of Diagnostic Tests
2.5.3.1. Sensitivity.
2.5.3.2. Specificity
2.5.4. Relationship between Prevalence, Sensitivity and Specificity
2.5.5. Diagnostic Probability Ratio
2.5.6. Jouden Test
2.5.7. Threshold Value
2.5.8. Concordance Out Diagnostic Tests
2.5.8.1. Kappa Calculation

2.6. Sample Size in Epidemiological Studies
2.6.1. What Are Samples?
2.6.2. Terms Related to Sampling
2.6.2.1. Target Population
2.6.2.2. Population Study
2.6.2.3. Study Subjects
2.6.2.4. External and Internal Validity
2.6.3. Selection Criteria
2.6.4. Types of Sampling
2.6.4.1. Probabilistic
2.6.4.2. Non-Probabilistic
2.6.5. Sample Size Calculation
2.6.6. Sample Size for Estimating the Mean of a Population
2.6.7. Sample Size for Estimating Proportions
2.6.7.1. Sample Size Adjustments
2.6.7.2. Calculation of the Accepted Error for a Preset Sample
2.6.8. Sample Size for Estimating Difference Between Proportions
2.6.9. Sample Size for Estimating Mean Difference
2.6.10. Errors
2.6.10.1. Random Error
2.6.10.2. Systematic Error or Bias

2.7. Observational Analytical Studies in Epidemiological Studies
2.7.1. Effect Measures
2.7.1.1. Case-Control Studies: Odas Ratio
2.7.1.2. Cohort Studies: Relative Risk

2.7.2. Impact Measures
2.7.2.1. Attributable Risk in Exposures
2.7.2.2. Fraction Attributable in Exposures
2.7.2.3. Attributable Population Risk
2.7.2.4. Population Attributable Fraction
2.7.3. Confusion and Interaction
2.8. Experimental Studies in the Epidemiological Study
2.8.1. Types of Experimental Studies
2.8.2. Experimental Elements
2.8.3. Experimental Study Design
2.8.4. Statistical Analysis
2.8.4.1. Exposure Effect
2.9. Epidemiological Statistics
2.9.1. Types of Statistics
2.9.1.1. Analytics
2.9.1.2. Descriptive or Inferential
2.9.2. Relationship between Epidemiology and Biostatistics
2.10. Review in Clinical Epidemiological Research
2.10.1. Systematic Review and Meta-Analysis
2.10.2. Protocol
2.10.3. Hypothesis Origin
2.10.4. Selection of the Study Population
2.10.4.1. Information Search
2.10.4.2. Inclusion Criteria
2.10.5. Data Collection
2.10.5.1. Importance of Source and Measurement of Data
2.10.6. Combination Methods
2.10.6.1. Mantel-Haensel Method
2.10.7. Heterogeneity Studies
2.10.8. Publication Bias
2.10.9. Health Significance of Meta-Analysis

Module 3. Approach to Veterinary Clinical Trials in Different Veterinary Settings Laboratories and Farms

3.1. Biology and Animal Management
3.1.1. Interaction Between Animals and Their Environment
3.1.2. Species Criteria
3.1.2.1. Mammals
3.1.2.2. Birds
3.1.2.3. Reptiles
3.1.2.4. Amphibians
3.1.2.5. Fish
3.1.3. Procedures
3.1.3.1. Substance Administration
3.1.3.2. Sample Collection
3.1.3.3. Surgical Procedures
3.1.4. Animal Pain and Suffering
3.1.4.1. Pain Recognition
3.1.4.2. Euthanasia
3.2. Veterinarians' Role in Different Veterinary Fields
3.2.1. Advantages and Disadvantages in the Different Veterinary Fields
3.2.1.1. Communication.
3.2.2. Adapting Protocols to the Study Environment
3.2.2.1. Veterinarian's Responsibilities
3.2.3. Informed consent
3.3. Special Considerations in the Practice of Clinical Trials in Laboratories and on Farms
3.3.1. Structure and Sites for Clinical Trials
3.3.1.1. Study Location Importance
3.3.1.2. Role of Laboratories
3.3.1.3. The Role of Farms
3.3.2. Shipping and Handling of Samples and Medical Products
3.3.3. Evolution of Anti-Parasitic Products
3.3.4. Application and Therapeutics of Vaccines

3.3.5. Responsible Antibiotic Use
3.3.5.1. Resistance Surveillance and Monitoring
3.4. Clinical Trials in the Scope of Aquaculture
3.4.1. Study Planning
3.4.1.1. Environmental Requirements
3.4.1.2. Access to Study Sites
3.4.1.3. Working Conditions: Personnel and Equipment
3.4.2. Protocol Development
3.4.3. Types of Research Substances
3.4.3.1. Nutritional Treatments
3.4.3.2. Immersion Baths
3.4.3.3. Vaccines
3.4.4. Design and Procedures
3.4.5. Sampling
3.4.6. Data Processing
3.5. Clinical Trials in the Scope of Poultry
3.5.1. Special Conditions in Poultry Farming
3.5.1.1. Study Structure
3.5.2. Study Planning
3.5.3. Protocol Development
3.5.4. Data Processing
3.6. Clinical Trials in Companion Animals
3.6.1. Pet Therapy Industry
3.6.2. Pet Characteristics
3.6.3. Protocol Development
3.6.4. Design and Procedures
3.6.5. Working Conditions: Personnel and Equipment
3.6.5.1. Protection and Precaution
3.6.6. Study Purpose
3.7. Clinical Trials in Pig Farming
3.7.1. The Pig Industry in Recent Years
3.7.1.1. Meat Quality
3.7.1.2. Industry Structure
3.7.1.3. Medical Products and the Industry
3.7.2. Good Practices and Organization of Trials
3.7.2.1. Participant Considerations
3.7.2.2. Research Site Choice
3.7.3. Performance of Procedures
3.7.3.1. Practical Applications
3.8. Clinical Trials in Cattle
3.8.1. Test Conditions and Approvals
3.8.2. Study Sites
3.8.2.1. Today's Cattle Industry
3.8.2.2. Choice of Site
3.8.3. Livestock Transportation
3.8.4. Test Substance Considerations
3.8.5. Trial Inclusion and Exclusion Criteria
3.8.5.1. Immune Status and Weaning
3.8.5.2. Signs of Disease
3.8.6. Practical Considerations
3.8.6.1. Design and Procedures
3.8.6.2. Monitoring of Animals and Personnel
3.9. Clinical Trials in Sheep and Goats
3.9.1. Small Ruminant Industry
3.9.2. Good Practices and Organization of Trials
3.9.2.1. Trail Conditions
3.9.2.2. Protocol Development
3.9.3. Studies Site Choice
3.9.4. Working Conditions: Personnel and Equipment
3.9.5. Trail Monitoring
3.10. Clinical Trials in Equids
3.10.1. Researchers' Role in this Area of Study
3.10.2. Protocol Development

3.10.2.1. Important Aspects of Treatments
3.10.2.2. Importance of Standardized Procedures
3.10.3. Recruitment of Individuals
3.10.3.1. The Importance of Equine Aptitude
3.10.3.2. How to Choose the Sample: Age, Breed, Feed and Fitness
3.10.4. Research Site Planning
3.10.5. Unforeseen Events and Problems During the Trial

Module 4. Veterinary Clinical Trial I. Design and Methodology

4.1. Veterinary Clinical Trials
4.1.1. Veterinary Clinical Trial Research
4.1.2. Conditions for Conducting a Veterinary Clinical Trial Investigation
4.1.3. Types of Veterinary Clinical Trials
4.1.3.1. Types of Trials According to the Study Design
4.1.3.2. Parallelisms
4.1.3.3. Crusader
4.1.3.4. In Pairs
4.1.3.5. Sequentials
4.2. Identifying Sources of Information for a Veterinary Clinical Trial
4.2.1. How To Find Information We Are Interested In
4.2.1.1. Choice of Source
4.2.1.2. Resources and Access Modes
4.2.1.3. How to Search for the Best Evidence on a Topic
4.3. Elaboration of a Protocol for the Conduct of a Clinical Trial with Veterinary Medication
4.3.1. General Information
4.3.2. Justification and Objectives
4.3.3. Test Outline
4.4. Design of the Veterinary Clinical Trials
4.4.1. Selection of Individuals
4.4.2. Inclusion/Exclusion Criteria

4.4.3. Treatment
4.4.4. Destination of Study Animals, Products Derived from Study Animals and Products under Clinical Investigation and Control Products
4.4.5. Adverse Events (AEs)

4.5. Methodology in Veterinary Clinical Trial Research
4.5.1. Hypotheses
4.5.2. Randomization
4.5.3. City
4.5.4. Sampling
4.5.5. Uncontrolled Trials
4.5.6. Controlled Trials
4.5.6.1. Open
4.5.6.2. Blind
4.5.6.3. Double-Blind
4.5.6.4. Triple-Blind
4.5.6.5. Pilot

4.6. Methodological Procedures in a Veterinary Clinical Trial (VCT)
4.6.1. Discrimination Between CD in Humans and Animals
4.6.2. Differences
4.6.3. Implementation
4.6.4. External and Internal Validity
4.6.5. Variables:
4.6.6. Consent
4.6.7. Reproducibility
4.6.8. Risk

4.7. Evaluation of the Efficiency of the Veterinary Clinical Trial.
4.7.1. Statistics
4.7.2. Records Management

4.7.3. Annexes Attached to Protocol
4.7.4. Changes in Protocol
4.7.5. References
4.8. Research Quality in a Veterinary Clinical Trial
4.8.1. Scientific Aspects
4.8.2. Risk-Benefit Assessment
4.9. Ethical Principles in a Veterinary Clinical Trial
4.9.1. Historical Background.
4.9.2. Ethical Codes
4.9.3. Application of Ethical Principles

Module 5. Veterinary Clinical Trials II. Trial Treatment

5.1. Description of Trail Treatment
5.1.1. What Does the Dose Description, Interval, Route and Form of Administration and Duration of the Treatment to be Trialed Depend on?
5.1.2. Criteria for the Creation of Patterns Throughout the Trial
5.2. Application of Special Rules to the Trail Treatment
5.2.1. Situations for Application of Special Rules to Trail Treatment
5.2.2. Measures to Assess Therapeutic Compliance in Special Situations
5.2.2.1. Examples of Special Situations
5.3. Response to Treatments
5.3.1. Data Collection
5.4. Methods and Evaluation of Treatment Response
5.4.1. Description of the Methods Used for Response Assessment and Quality Control
5.4.4.1. Complementary Tests: Laboratory Tests, Diagnostic Imaging, Electrocardiogram, etc.
5.4.2. Evaluation of Data Obtained as a Function of Response
5.5. Monitoring. Trial Treatment Plan
5.5.1. Monitoring Plan
5.5.2. Research Timeline
5.5.3. Types of Schedules
5.6. Main Problems in the Methodological Approaches to Treatment in the Trial
5.6.1. Incorrect Documentation
5.6.2. Samples
5.6.2.1. Missing Samples
5.6.2.2. Delayed Samples
5.6.2.3. Forgotten Parameters
5.6.2.4. Incorrect Sampling Times
5.6.2.5. Laboratory Kit Problems
5.7. Specialized Methodology in Treatment I
5.7.1. Clinical Trials in Veterinary Oncology
5.7.1.1. Trail Phases
5.7.1.2. Therapeutic Targets
5.7.1.3. Biological Samples
5.7.1.4. Bioequivalence
5.8. Specialized Methodology in Treatment II
5.8.1. Clinical Trials in Veterinary Infectious Pathology I
5.8.1.1. Analysis Objectives
5.8.1.2. Epidemiological Clinical Trials Methodology
5.9. Specialized Methodology in Treatment III
5.9.1. Clinical Trials in Veterinary Infectious Pathology. Prevention and Control of Veterinary Infectious Pathology II
5.9.1.1. Prevention and Control of the Disease
5.9.1.1.1. Institutional Strategies
5.9.1.2. Risk Evaluation
5.10. Specialized Methodology in Treatment IV
5.10.1. Clinical Trials in Veterinary Neurology
5.10.1.1. Neurology Research
5.10.1.1.1. Research Areas
5.10.1.2. Field Work
5.10.1.3. Interpreting Results

Module 6. Genetic Diseases in Veterinary Clinical Trials (VCT). Veterinary Genetic Epidemiology

6.1. Cities
- 6.1.1. Attributes to Highlight in a Population
  - 6.1.1.1. Common and Ethnicity Attributes
  - 6.1.1.2. Methods and Estimates of Gene Phylogeny in Populations
  - 6.1.1.3. Populations, Social Level and Health Plan: Epidemiological Influence

6.2. Distributions of Disease Traits in Animal Populations. Genetic Databases
- 6.2.1. Genetic Traits and Diseases
  - 6.2.1.1. Qualitative Determinants of Disease
  - 6.2.1.2. Quantitative Traits and Disease Susceptibility
  - 6.2.1.3. Genetic Disease Databases and their Application to Epidemiology
  - 6.2.1.4. NCBI Searches
  - 6.2.1.5. Species-Specific Databases on Genetic Diseases

6.3. Interaction in the Genetic Epidemiological Triad
- 6.3.1. Elements of the Epidemiological Triad
- 6.3.2. Host, Genetic Make-Up and Environment
  - 6.3.2.1. Genetic Make-Up and its Relevance
  - 6.3.2.2. Genotype-Environment Interaction

6.4. Genetic Epidemiology in the Light of Koch's Postulates. Part I
- 6.4.1. Epidemiology of Cytogenetic Animals
- 6.4.2. Diseases Due to Genetic Alterations of Major Effect
  - 6.4.2.1. Cause of Disease: Single Gene Disorders "Monogenic"
  - 6.4.2.2. Genetic Heterogeneity in Monogenic Diseases

6.5. Genetic Epidemiology in the Light of Koch's Postulates. Part II
- 6.5.1. Multifactorial Cause of Disease: Genetic Component
  - 6.5.1.1. High Heritability
  - 6.5.1.2. Low Heritability
- 6.5.2. Multifactorial Cause of Disease: Environmental Component
  - 6.5.2.1. Infectious Causes as an Environmental Component
  - 6.5.2.2. Cause of Disease and Environmental Exposure
- 6.5.3. Interaction between Components

6.6. Data Collection and Analysis Strategy: Population Studies vs. Family Studies
- 6.6.1. Population Studies
  - 6.6.1.1. Evaluation of the Distribution of Traits in Populations
  - 6.6.1.2. Identification of Risk Factors and their Importance
- 6.6.2. Family Studies
  - 6.6.2.1. Evaluation of Trait Distribution in Families
  - 6.6.2.2. Identification of Risk Factors, Aggregation and their Importance
- 6.6.3. Combining Population and Family Studies

6.7. Data Collection Strategy and Analysis: Components of a Study of a Common Complex Disease
- 6.7.1. Measuring Disease Burdens
  - 6.7.1.1. Different Ways of Measuring Disease Burdens
- 6.7.2. Morbidity Measures
  - 6.7.2.1. Cumulative Incidence
  - 6.7.2.2. Prevalence
  - 6.7.2.3. Disease Duration

6.8. Main Analytical Study Designs
- 6.8.1. Cross-Sectional Design (Current Prevalence)
- 6.8.2. Cohort Design (Prospective)
- 6.8.2. Case-Control Design (Retrospective)
- 6.8.3. Association Measures

6.9. Data Analysis and Risk Calculations
- 6.9.1. Association Measures
  - 6.9.1.1. Relative Risk Estimates
  - 6.9.1.2. Odds Ratio (OR)
- 6.9.2. Impact Measures
  - 6.9.2.1. Attributable Risk (AR)
  - 6.9.2.2. Population Attributable Risk (PAR)

6.10. Estimates, Data Evaluation and Calculations in SPSS
- 6.10.1. Estimates
- 6.10.2. Assessment of Information
- 6.10.3. SPSS Calculations

Module 7. Principal Investigators, Sponsors and Monitors of Veterinary Clinical Trials (VCTs)

7.1. Professional Approach to Clinical Trials
- 7.1.1. Business, Science and Clinical Trials
  - 7.1.1.1. Clinical Trials in the Public and Private Sector
  - 7.1.1.2. Public-Private Preliminary Interaction

7.2. Veterinary Profession in the Context of Clinical Trials
- 7.2.1. Adequacy of the Veterinary Profession in Clinical Trials
- 7.2.2. Reasons for Conducting Clinical Trials
- 7.2.3. Registration and Animal Protection in Veterinary Clinical Trials
- 7.2.4. Follow-Up Veterinary Care

7.3. Principal Investigator's Guide
- 7.3.1. Researchers and Companies Technical Assistance Companies
  - 7.3.1.1. Search Resources for Public and Private Companies
  - 7.3.1.2. Budget Preparation Models
- 7.3.2. Responsibilities and Regulatory Committees
  - 7.3.2.1. Responsibilities of Technical Assistance Centers
  - 7.3.2.2. PI Responsibilities
  - 7.3.2.3. Other Participants with Responsibilities
- 7.3.3. Budget Development and Negotiation
  - 7.3.3.1. Sponsors and their Types
  - 7.3.3.2. Role of the Principal Investigator
  - 7.3.3.3. Study Activation and Preliminary Reports

7.4. The Research Equipment in Veterinary Clinical Trials I
- 7.4.1. Research Equipment and Data Management
  - 7.4.1.1. Principal Investigator
  - 7.4.1.2. Other Research Participants
  - 7.4.1.3. Clinical Trial Subjects
  - 7.4.1.4. Databases: Management and Administration

7.5. The Research Team and Data Quality Control II
- 7.5.1. Data Sources
- 7.5.2. Choice of Database Collection and Archiving System
- 7.5.3. Data Quality Control
- 7.5.4. Data Security Monitoring and Audits

7.6. Good Clinical Practices, Protocol Agreement and Participant Evaluation
- 7.6.1. Guarantees of Research Integrity and Protection of Participant's Security
- 7.6.2. Timing of Data Management Plans
- 7.6.3. Management of Research Personnel and Resources in Context
- 7.6.4. Automated Systems

7.7. The Principal Investigator (PI) in the Veterinary Clinical Trial
- 7.7.1. Administration and Financial Management of the Sponsored Program
- 7.7.2. Conflicts of Interest
- 7.7.3. Research Participant Protection
- 7.7.4. Environmental Health and Safety
- 7.7.5. Patents and Inventions
- 7.7.6. Export Controls

7.8. Veterinary Population Involved in Biomedical Research
- 7.8.1. Veterinary Population Involved in Biomedical Research
- 7.8.2. Relevant Activity Areas
- 7.8.3. Professional Merits

7.9. Sponsors of Veterinary Clinical Trials
- 7.9.1. Private Sector
- 7.9.2. Foundations
- 7.9.3. Other Promotion Sources

7.10. The Monitor: Training and Primary Function
- 7.10.1. Monitor Training and Designation
  - 7.10.1.1. Preparation, Attitude and Qualification
  - 7.10.1.2. Sponsors
- 7.10.2. Reporting Protocols and Forms
  - 7.10.2.1. Protocol Reviews
  - 7.10.2.2. Case Report Forms
  - 7.10.2.3. Final Study Reports (According to VICH GL9 Competencies)
- 7.10.3. Interaction with Researchers, Laboratories and Laboratory Personnel
  - 7.10.3.1. IP Selection
  - 7.10.3.2. Laboratory Selection
  - 7.10.3.3. Location Selection

Module 8. Pharmacovigilance and Pharmacoeconomics

8.1. Safety of Veterinary Medications in Animals
- 8.1.1. Design and Implementation of the Pharmacovigilance System in a Clinical Trial
- 8.1.2. Elaboration and Updating of Standard Operating Procedures (SOPs).
- 8.1.3. Initial Assessment

8.2. Personal Safety
- 8.2.1. Active Substance Toxicity Data
- 8.2.2. Toxicity Studies
- 8.2.3. Exposure Scenarios
- 8.2.4. Risk Management

8.3. Environmental Safety
- 8.3.1. Active Substance Metabolites
- 8.3.2. Biodegradation
- 8.3.3. Recommended Studies

8.4. Adverse Event Management
- 8.4.1. Registration (Adverse Reactions, Side Effects and Expected Unfavorable Reactions)
- 8.4.2. Control Methods
- 8.4.3. Adverse Events Communication.

8.5. Summary of Product Characteristics (SPC) for Veterinary Medication

8.6. Elaboration and Maintenance of the Pharmacovigilance System Description
- 8.6.1. Detailed Description of the Pharmacovigilance System
- 8.6.2. Qualified Person Responsible for Pharmacovigilance (QPPV)
- 8.6.3. Organization
- 8.6.4. Databases
- 8.6.5. Quality Management Systems

8.7. Periodic Safety Reports (PSRs)
- 8.7.1. VedDRA Code (Veterinary Dictionary for Regulatory Activities)

8.8. Risk-Benefit Analysis
- 8.8.1. Concept and Components
- 8.8.2. Quantitative Methods
  - 8.8.2.1. Relationship Between Benefit and Harm Impact Measures
  - 8.8.2.2. Incremental Benefit-Risk Ratio
  - 8.8.2.3. Multi-Criteria Analysis
- 8.8.3. Cohort Simulation

8.9. Crisis Management
- 8.9.1. Risk Assessment
- 8.9.2. Response Coordination
- 8.9.3. Risk and Crisis Communication

8.10. Pharmacoeconomics
- 8.10.1. Cost-Benefit Analysis
- 8.10.2. Cost-Effectiveness Analysis
- 8.10.3. Cost-Utility Analysis
- 8.10.4. Cost Minimization

Module 9. Legislation Applicable to Veterinary Clinical Trials

9.1. European Legislation and Regulations I
- 9.1.1. Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 Amending Regulation (EC) No. 726/2004 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency
- 9.1.2. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and Repealing Directive 2001/82/EC.

9.2. European Legislation and Regulations II
- 9.2.1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicinal Products Agency
  - 9.2.1.1. Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 Concerning the Examination of Variations to the Terms of Marketing Authorizations for Medicinal Products for Human Use and Veterinary Medicinal Products.

9.3. European Legislation and Regulations III
- 9.3.1. Commission Regulation (EC) No. 1234/2008 of 24 November 2008 Concerning the Examination of Variations to the Terms of Marketing Authorizations for Medicinal Products for Human Use and Veterinary Medicinal Products

9.4. European Regulations IV

9.5. European Medicines Agency (EMA)
- 9.5.1. Organization
- 9.5.2. Functions

Module 10. Veterinary Clinical Trials II. Management, Start-ups and Commissioning

10.1. Clinical Trial Management Preclinical Development
- 10.1.1. Preclinical Development
  - 10.1.1.1. Animal Experimentation Committees
- 10.1.2. Exploratory Clinical Trial
- 10.1.3. Regulatory Clinical Trial

10.2. Clinical Trial Authorization Process
- 10.2.1. Application for a Veterinary Research Product
- 10.2.2. Request for a Veterinary Clinical Trial

10.3. Documents at the Beginning of the Clinical Trial
- 10.3.1. Contract Management
- 10.3.2. Clinical Trial Protocol

10.4. Clinical Trial Initiation and Start-Up
- 10.4.1. Initial Visit and Center Opening
- 10.4.2. Data Collection Notebooks (DCNs)
- 10.4.3. Electronic Data Capture (EDC)

10.5. Clinical Trial Documentation Archive
- 10.5.1. Medication Shipment and Management
- 10.5.2. Documentation Custody

10.6. Final Report
- 10.6.1. Center Closures
- 10.6.2. Clinical Trial Documentation Audit
- 10.6.3. Audit of Data Management Activities

10.7. Laboratory Certification
- 10.7.1. Laboratory Certification: GMP, GLP, ISO
- 10.7.2. Pharmacopoeias

10.8. Regulatory Dossier Structure
- 10.8.1. Document Management
- 10.8.2. Validation of the Internal Structure
- 10.8.3. Electronic Communication with Regulatory Agencies

10.9. Writing Results
- 10.9.1. Publication of Clinical Trials in Scientific Journals

10.10. CONSORT Recommendations

Don't think twice and choose a program that will enable you to keep up to date with the latest developments in animal ethics ensure their safety in the clinical and research environment"

06

Methodology

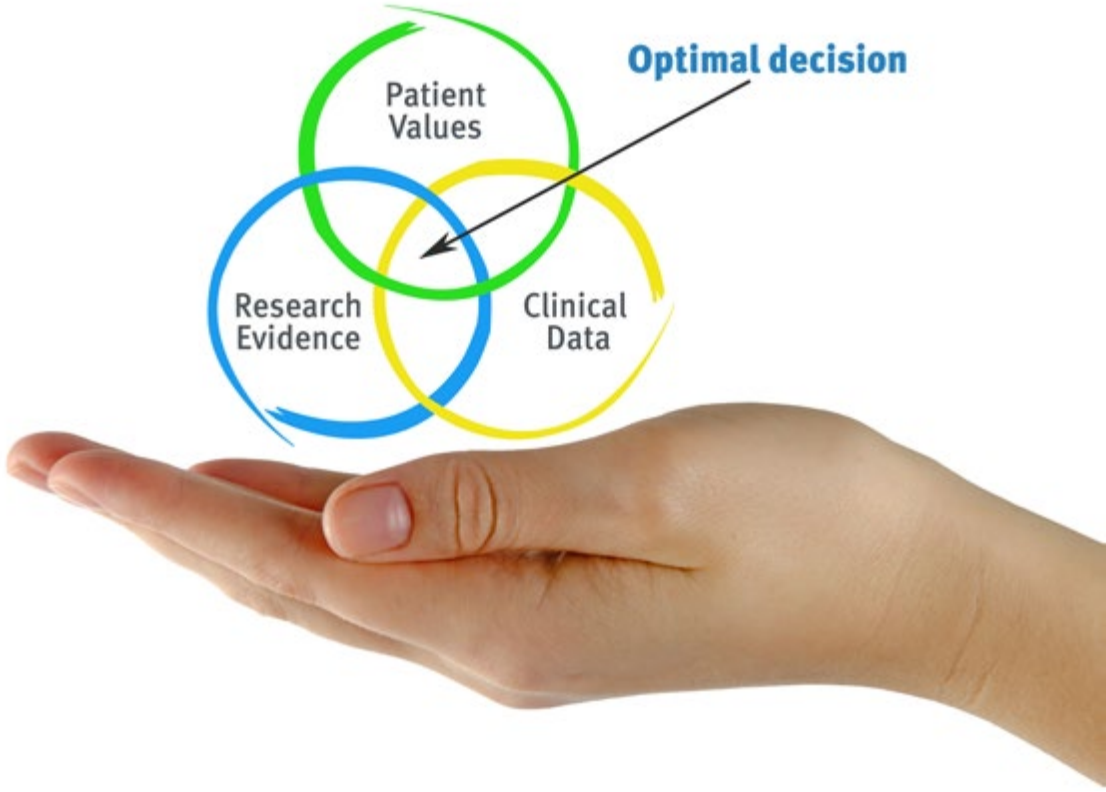
This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning.**
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

Discover Relearning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"

At TECH we use the Case Method

What should a professional do in a given situation? Throughout the program you will be presented with multiple simulated clinical cases based on real patients, where you will have to investigate, establish hypotheses and, finally, resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Specialists learn better, faster, and more sustainably over time.

With TECH you will experience a way of learning that is shaking the foundations of traditional universities around the world.



According to Dr. Gérvas, the clinical case is the annotated presentation of a patient, or group of patients, which becomes a "case", an example or model that illustrates some peculiar clinical component, either because of its teaching power or because of its uniqueness or rarity. It is essential that the case is based on current professional life, in an attempt to recreate the actual conditions in a veterinarian's professional practice.

Did you know that this method was developed in 1912, at Harvard, for law students? The case method consisted of presenting students with real-life, complex situations for them to make decisions and justify their decisions on how to solve them. In 1924, Harvard adopted it as a standard teaching method"

The effectiveness of the method is justified by four fundamental achievements:

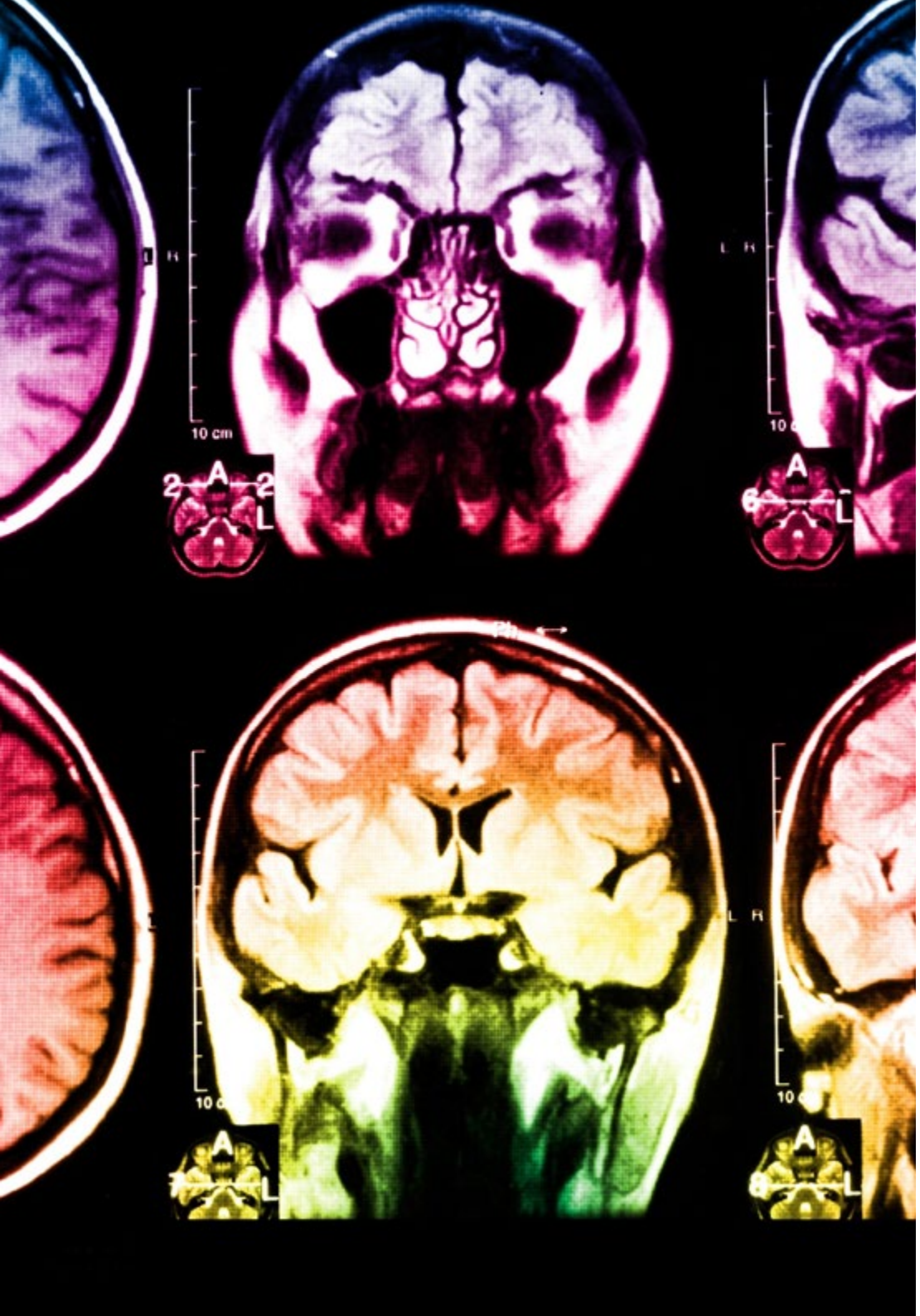
1. Veterinarians who follow this method not only manage to assimilate concepts, but also develop their mental capacity through exercises to evaluate real situations and knowledge application
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts are understood more efficiently, given that the example situations are based on real-life.
4. The feeling that the effort invested is effective becomes a very important motivation for veterinarians, which translates into a greater interest in learning and an increase in the time dedicated to working on the course.

Relearning Methodology

At TECH we enhance the case method with the best 100% online teaching methodology available: Relearning.

This university is the first in the world to combine the study of clinical cases with a 100% online learning system based on repetition, combining a minimum of 8 different elements in each lesson, a real revolution with respect to the mere study and analysis of cases.

Veterinarians will learn through real cases and by resolving complex situations in simulated learning environments. These simulations are developed using state-of-the-art software to facilitate immersive learning.



At the forefront of world teaching, the Relearning method has managed to improve the overall satisfaction levels of professionals who complete their studies, with respect to the quality indicators of the best online university (Columbia University).

With this methodology more than 65,000 veterinarians have been trained with unprecedented success in all clinical specialties, regardless of the surgical load. Our teaching method is developed in a highly demanding environment, where the students have a high socio-economic profile and an average age of 43.5 years.

Relearning will allow you to learn with less effort and better performance, involving you more in your training, developing a critical mindset, defending arguments, and contrasting opinions: a direct equation for success.

In our program, learning is not a linear process, but rather a spiral (learn, unlearn, forget, and re-learn). Therefore, we combine each of these elements concentrically.

The overall score obtained by TECH's learning system is 8.01, according to the highest international standards.

This program offers the best educational material, prepared with professionals in mind:

Study Material

All teaching material is produced by the specialists who teach the course, specifically for the course, so that the teaching content is highly specific and precise.

These contents are then applied to the audiovisual format, to create the TECH online working method. All this, with the latest techniques that offer high quality pieces in each and every one of the materials that are made available to the student.

Latest Techniques and Procedures on Video

TECH introduces students to the latest techniques, the latest educational advances and to the forefront of current and procedures of veterinary techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch the videos as many times as you like.

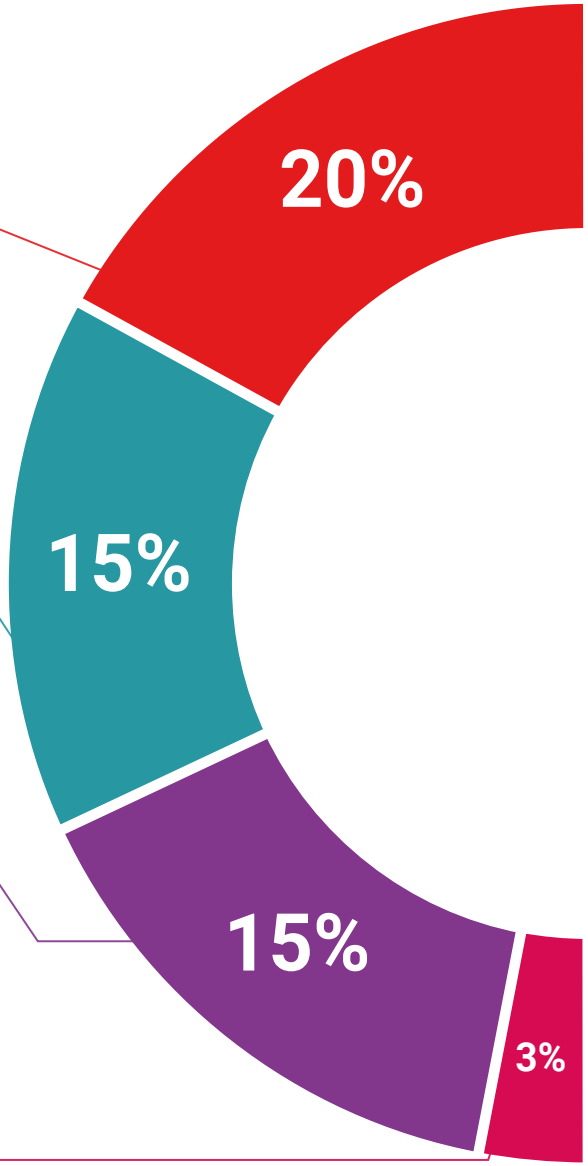
Interactive Summaries

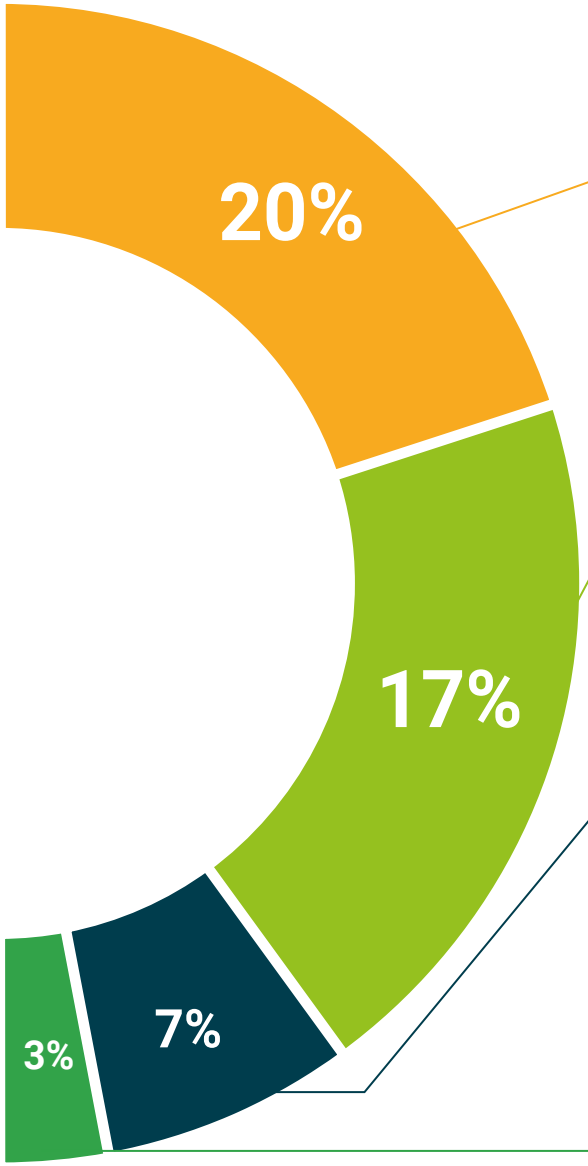
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

This exclusive educational system for presenting multimedia content was awarded by Microsoft as a "European Success Story".

Additional Reading

Recent articles, consensus documents and international guidelines, among others. In TECH's virtual library, students will have access to everything they need to complete their course.





Expert-Led Case Studies and Case Analysis

Effective learning ought to be contextual. Therefore, TECH presents real cases in which the expert will guide students, focusing on and solving the different situations: a clear and direct way to achieve the highest degree of understanding.

Testing & Retesting

We periodically evaluate and re-evaluate students' knowledge throughout the program, through assessment and self-assessment activities and exercises, so that they can see how they are achieving their goals.

Classes

There is scientific evidence suggesting that observing third-party experts can be useful.

Learning from an Expert strengthens knowledge and memory, and generates confidence in future difficult decisions.

Quick Action Guides

TECH offers the most relevant contents of the course in the form of worksheets or quick action guides. A synthetic, practical, and effective way to help students progress in their learning.

07

Certificate

The Professional Master's Degree in Veterinary Clinical Trials guarantees students, in addition to the most rigorous and up-to-date education, access to a certificate issued by TECH Technological University.

Successfully complete this program and receive your university qualification without having to travel or fill out laborious paperwork"

This **Professional Master's Degree in Veterinary Clinical Trials** contains the most complete and up-to-date educational program on the market.

After the student has passed the assessments, they will receive their corresponding **Professional Master's Degree** diploma issued by **TECH Technological University** via tracked delivery*.

The diploma issued by **TECH Technological University** will reflect the qualification obtained in the Professional Master's Degree, and meets the requirements commonly demanded by labor exchanges, competitive examinations, and professional career evaluation committees.

Title: **Professional Master's Degree in Veterinary Clinical Trials**

Official Nº of Hours: **1,500 h.**

tech technological university

Awards the following

DIPLOMA

to

Mr./Ms. _____, with identification number _____.

For having successfully passed and accredited the following program

PROFESSIONAL MASTER'S DEGREE

in

Veterinary Clinical Trials

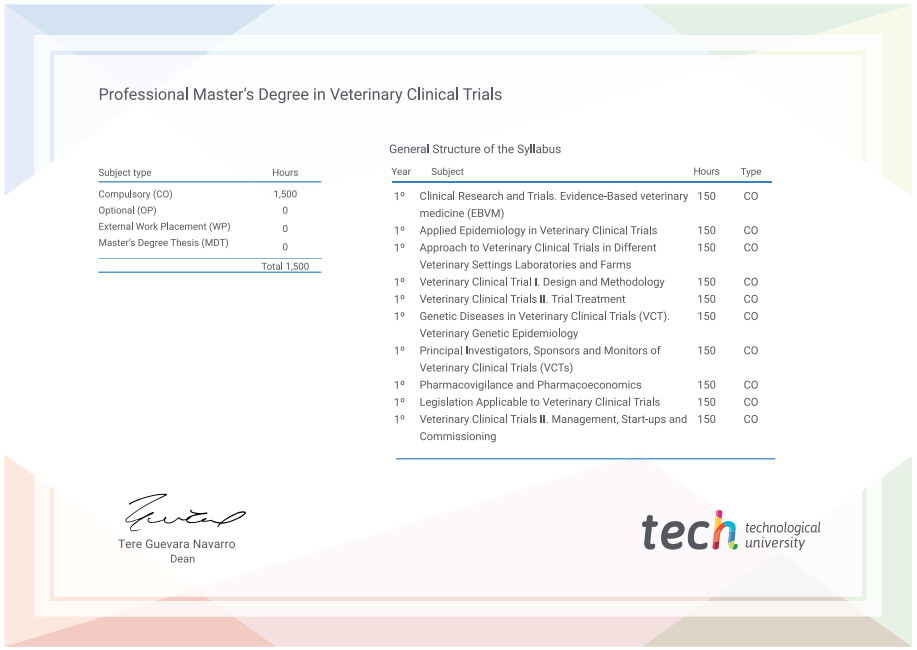
This is a qualification awarded by this University, equivalent to 1,500 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH is a Private Institution of Higher Education recognized by the Ministry of Public Education as of June 28, 2018.

June 17, 2020

Tere Guevara Navarro
Dean

This qualification must always be accompanied by the university degree issued by the competent authority to practice professionally in each country. Unique TECH Code: AFWORD23S techtitute.com/certificates


Professional Master's Degree in Veterinary Clinical Trials

Subject type	Hours
Compulsory (CO)	1,500
Optional (OP)	0
External Work Placement (WP)	0
Master's Degree Thesis (MDT)	0
	Total 1,500

General Structure of the Syllabus

Year	Subject	Hours	Type
1º	Clinical Research and Trials. Evidence-Based veterinary medicine (EBVM)	150	CO
1º	Applied Epidemiology in Veterinary Clinical Trials	150	CO
1º	Approach to Veterinary Clinical Trials in Different Veterinary Settings Laboratories and Farms	150	CO
1º	Veterinary Clinical Trial I. Design and Methodology	150	CO
1º	Veterinary Clinical Trials II. Trial Treatment	150	CO
1º	Genetic Diseases in Veterinary Clinical Trials (VCT). Veterinary Genetic Epidemiology	150	CO
1º	Principal Investigators, Sponsors and Monitors of Veterinary Clinical Trials (VCTs)	150	CO
1º	Pharmacovigilance and Pharmacoeconomics	150	CO
1º	Legislation Applicable to Veterinary Clinical Trials	150	CO
1º	Veterinary Clinical Trials II. Management, Start-ups and Commissioning	150	CO

Tere Guevara Navarro
Dean

tech technological university

*Apostille Convention. In the event that the student wishes to have their paper diploma issued with an apostille, TECH EDUCATION will make the necessary arrangements to obtain it, at an additional cost.

tech technological university

Professional Master's Degree
Veterinary Clinical Trials

- Modality: **online**
- Duration: **12 months**
- Certificate: **TECH Technological University**
- Dedication: **16h/week**
- Schedule: **at your own pace**
- Exams: **online**

Professional Master's Degree
Veterinary Clinical Trials

tech technological university