

# Postgraduate Diploma

## Management and Administration of Veterinary Clinical Trials



## Postgraduate Diploma Management and Administration of Veterinary Clinical Trials

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

Website: [www.techtute.com/us/veterinary-medicine/postgraduate-diploma/postgraduate-diploma-management-administration-veterinary-clinical-trials](http://www.techtute.com/us/veterinary-medicine/postgraduate-diploma/postgraduate-diploma-management-administration-veterinary-clinical-trials)

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# 01

# Introduction

In the process of studying the efficacy and safety of a drug in the veterinary field, multiple areas are involved. One of the most essential areas is Management and Administration, for which specific and specialized knowledge is required, which is in great demand in the labor market. For this reason, TECH has designed a program that seeks to provide students with the necessary skills and competencies to be able to approach their professional work as efficiently as possible. In this way, throughout the program we delve into topics such as the History of Clinical Research or the Design, Methodology and implementation of a Veterinary Clinical Trial. All this, through a convenient 100% online modality and the most complete and up-to-date program on the market





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*Update your knowledge and acquire new skills in Management and Administration of Veterinary Clinical Trials”*

In order to carry out a Clinical Trial in the Veterinary field, multiple processes, procedures and protocols take place, which are the ones that allow this study of the characteristics and usefulness of a drug to be successful. This is why Management and Administration are so important in this area, as well as professionals with specific knowledge in this sector

This is the reason why TECH has designed a Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials, to provide students with new and better skills with which to face their professional work, with full capacity and guaranteed success in their jobs. In this way, this program delves into topics such as the Scientific Method, Statistical Principles, Technical Documentation, Management, Special Standards or Evaluation Methods and response in Veterinary Clinical Trials

All this, in a convenient 100% online mode that allows students to organize their schedules and studies as they see fit, without the need to travel and with the possibility of accessing all the content with any device with an Internet connection. In addition, with the most dynamic multimedia materials, the most complete information and the latest teaching technologies at your disposal

This **Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials** contains the most complete and up-to-date scientific program on the market. The most important features include:

- ♦ The development of case studies presented by experts in Management and Administration of Veterinary Clinical Trials
- ♦ 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 the self-assessment process can be carried out 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



*Achieve excellence in Management and Administration in the veterinary environment"*

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*The most comprehensive and innovative information on Management, Initiation and Start-up of Veterinary Clinical Trials"*

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

Its 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 an immersive education programmed to learn in real situations

The design of this program focuses on Problem-Based Learning, by means of which the professional must try to solve the different professional practice situations that are presented throughout the academic course. For this purpose, the student will be assisted by an innovative interactive video system created by renowned experts

*You will be able to enjoy all the content available in the Virtual Campus from the first day and 100% online*

*Hone your skills in Preclinical Development and Laboratory Certification*



# 02 Objectives

The objective of this Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials is to provide students with new skills and specific knowledge in this area, so that they can face their professional work as effectively as possible. All this, through the most complete and up-to-date contents in the educational market







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*Reach your most demanding goals thanks to TECH and the most complete program in Clinical Trial Management and Administration”*



## General Objectives

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- ♦ 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 a Clinical Investigation
- ♦ 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





## Specific Objectives

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### **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. The 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 3. The 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 trial 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

### **Module 4. The Veterinary Clinical Trials III. Treatment Trial**

- ♦ 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

03

# Course Management

In its quest for educational excellence, TECH has designed a team of experts composed of outstanding professionals with extensive backgrounds in this field, who have poured their most specialized knowledge into all the material. In this way, the most complete and up-to-date theoretical and practical contents can be offered to the student, which will meet the highest expectations



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*Consult directly with the teachers throughout the process and succeed with the best experts in Veterinary Clinical Trials”*

## Management



### Dr. Martín Palomino, Pedro

- ♦ Manager of ALJIBE Veterinary Laboratory
- ♦ Senior program researcher at the Castilla-La Mancha Research Center Spain
- ♦ PhD in Veterinary Medicine from the University of Extremadura
- ♦ Diploma in Public Health from the National School of Health (ENS) at the Carlos III Health Institute (ISCIII)
- ♦ Master's Degree in Swine Technology from the Faculty of Veterinary Medicine of Murcia at the University of Murcia
- ♦ Professor of Infectious Diseases, Zoonoses and Public Health at the Alfonso X el Sabio University



### Dr. Fernández García, José Luis

- ♦ Veterinary Doctor
- ♦ PhD in Veterinary Medicine from the University of Extremadura
- ♦ Graduate in Veterinary with Degree from the University of Extremadura
- ♦ Master's Degree in Biotechnology from the CNB Severo Ochoa
- ♦ Adjunct Veterinarian, University of Extremadura

## Professors

### Dr. Rojo González, José Antonio

- ♦ Small Animal Clinical Veterinarian
- ♦ Small Animal Veterinarian
- ♦ Teacher in Specialized Education Centers
- ♦ Degree in Veterinary Medicine from the University of Extremadura. Cáceres, Spain

### 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 of the Neurosurgery Service at the San Carlos Clinical Hospital
- ♦ Doctor in Biomedical Research from the Complutense University of Madrid
- ♦ Degree in Veterinary Medicine from Alfonso X El Sabio University
- ♦ Official Master's Degree in Veterinary Science Research from the Complutense University of Madrid
- ♦ Master's Degree in Integral Management of Veterinary Clinical Trials by Universidad Europea

### Mr. Pacheco Bermejo, Cristian

- ♦ Clinical Trials Nurse Specialist
- ♦ Nurse at Fresenius Medical Care Clinic Cáceres
- ♦ Emergency Department Nurse at the San Pedro de Alcántara University Hospital Cáceres
- ♦ Nurse of the Surgical Block of the University Hospital. Cáceres
- ♦ Nurse at Coria City Hospital. Coria
- ♦ Nurse at the Dr. José Vicente Martín Health Center Cáceres
- ♦ Graduate in Nursing from the University of Extremadura

### Mr. Bravo Acedo, Sara

- ♦ Veterinarian at Tragsatec
- ♦ Veterinary Clinical Trials Specialist
- ♦ Scientific and Research Staff in Food Science and Technology at the University of Extremadura
- ♦ Degree in Veterinary Medicine from the University of Extremadura
- ♦ Master's Degree in Meat Science and Technology, University of Extremadura, Spain
- ♦ Master's Degree in Health Sciences from the University of Extremadura, Spain
- ♦ Master's Degree in High School Teacher Training from the University of Extremadura
- ♦ Advanced Technician in Dietetics, Alfonso X el Sabio University

# 04

# Structure and Content

This syllabus has been designed and structured by leading experts in the field, who have created a precise, innovative and complete content, with which the student's most demanding needs will be satisfied. In addition, all materials follow the Relearning pedagogical methodology, which facilitates the assimilation of essential concepts in a natural, direct and dynamic way







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*Reach your highest goals in the workplace,  
thanks to TECH and the most efficient  
pedagogical methodology, Relearning”*

**Module 1. Clinical Research and Clinical 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: The Streptomycin Randomized Trial
- 1.2. Research. 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. 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 The 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. Ethics
    - 1.4.2.5. 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 ( $\alpha$ ) and Beta ( $\beta$ )
    - 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: Currently
- 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. Use of Experimental Animals
  - 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
  - 1.10.2.2.3. Ontological Codes
- 1.10.3. Legal Regulations
  - 1.10.3.1. Legal Aspects Regulations in Europe

## Module 2. The Veterinary Clinical Trial I. Design and Methodology

- 2.1. Veterinary Clinical Trials
  - 2.1.1. Veterinary Clinical Trial Research
  - 2.1.2. Conditions for Conducting a Veterinary Clinical Trial Investigation
  - 2.1.3. Types of Veterinary Clinical Trials
    - 2.1.3.1. Types of Trials According to the Study Design
    - 2.1.3.2. Parallelisms
    - 2.1.3.3. Crusader
    - 2.1.3.4. In Pairs
    - 2.1.3.5. Sequentials
- 2.2. Identifying Sources of Information for a Veterinary Clinical Trial
  - 2.2.1. How To Find Information We Are Interested In
    - 2.2.1.1. Choice of Source
    - 2.2.1.2. Resources and Access Modes
    - 2.2.1.3. How to Search for the Best Evidence on a Topic
- 2.3. Elaboration of a Protocol for the Conduct of a Clinical Trial with Veterinary Medication
  - 2.3.1. General Information
  - 2.3.2. Justification and Objectives
  - 2.3.3. Test Outline
- 2.4. Design of the Veterinary Clinical Trials
  - 2.4.1. Selection of Individuals
  - 2.4.2. Inclusion/Exclusion Criteria
  - 2.4.3. Treatment
  - 2.4.4. Destination of Study Animals, Products Derived from Study Animals and Products under Clinical Investigation and Control Products
  - 2.4.5. Adverse Events (AEs)

- 2.5. Methodology in Veterinary Clinical Trial Research
  - 2.5.1. Hypotheses
  - 2.5.2. Randomization
  - 2.5.3. City
  - 2.5.4. Sampling
  - 2.5.5. Uncontrolled Trials
  - 2.5.6. Controlled Trials
    - 2.5.6.1. Open
    - 2.5.6.2. Blind
    - 2.5.6.3. Double-Blind
    - 2.5.6.4. Triple-Blind
    - 2.5.6.5. Pilot
- 2.6. Methodological Procedures in a Veterinary Clinical Trial (VCT)
  - 2.6.1. Discrimination Between CD in Humans and Animals
  - 2.6.2. Differences
  - 2.6.3. Implementation
  - 2.6.4. External and Internal Validity
  - 2.6.5. Variables
  - 2.6.6. Consent
  - 2.6.7. Reproducibility
  - 2.6.8. Risk
- 2.7. Evaluation of the Efficiency of the Veterinary Clinical Trial
  - 2.7.1. Statistics
  - 2.7.2. Records Management
  - 2.7.3. Annexes Attached to Protocol
  - 2.7.4. Changes in Protocol
  - 2.7.5. References
- 2.8. Research Quality in a Veterinary Clinical Trial
  - 2.8.1. Legal Aspects
  - 2.8.2. Scientific Aspects
  - 2.8.3. Risk-Benefit Assessment

- 2.9. Ethical Principles in a Veterinary Clinical Trial
  - 2.9.1. Historical Background
  - 2.9.2. Ethical Codes
  - 2.9.3. Application of Ethical Principles

### Module 3. The Veterinary Clinical Trials II. Management, Start-ups and Commissioning

- 3.1. Clinical Trial Management Preclinical Development
  - 3.1.1. Preclinical Development
    - 3.1.1.1. Animal Experimentation Committees
  - 3.1.2. Exploratory Clinical Trial
  - 3.1.3. Regulatory Clinical Trial
- 3.2. Clinical Trial Authorization Process
  - 3.2.1. Application for a Veterinary Research Product
  - 3.2.2. Request for a Veterinary Clinical Trial
- 3.3. Documents at the Beginning of the Clinical Trial
  - 3.3.1. Contract Management
  - 3.3.2. Clinical Trial Protocol
  - 3.3.3. Informed Consent
- 3.4. Clinical Trial Initiation and Start-Up
  - 3.4.1. Initial Visit and Center Opening
  - 3.4.2. Data Collection Notebooks (DCNs)
  - 3.4.3. Electronic Data Capture (EDC)
- 3.5. Documentary Archive of a Clinical Trial
  - 3.5.1. Medication Shipment and Management
  - 3.5.2. Documentation Custody
- 3.6. Final Report
  - 3.6.1. Center Closures
  - 3.6.2. Clinical Trial Documentation Audit
  - 3.6.3. Audit of Data Management Activities
- 3.7. Laboratory Certification
  - 3.7.1. Laboratory Certification: GMP
  - 3.7.2. Laboratory Certification: GLP
  - 3.7.3. Laboratory Certification: ISO

- 3.8. Regulatory Dossier Structure
  - 3.8.1. Document Management
  - 3.8.2. Validation of the Internal Structure
  - 3.8.3. Electronic Communication with Regulatory Agencies
- 3.9. Results Writing
  - 3.9.1. Publication of Clinical Trials in Scientific Journals
- 3.10. CONSORT Recommendations

## Module 4. The Veterinary Clinical Trials III. Treatment Trial

- 4.1. Description of Trail Treatment
  - 4.1.1. What Does the Dose Description, Interval, Route and Form of Administration and Duration of the Treatment to be Trialed Depend on?
  - 4.1.2. Criteria for the Creation of Patterns Throughout the Trial
- 4.2. Application of Special Rules to the Trial Treatment
  - 4.2.1. Situations for Application of Special Rules to Trail Treatment
  - 4.2.2. Measures to Assess Therapeutic Compliance in Special Situations
    - 4.2.2.1. Examples of Special Situations
- 4.3. Response to Treatment
  - 4.3.1. Data Collection
- 4.4. Methods and Evaluation of Treatment Response
  - 4.4.1. Description of the Methods Used for Response Assessment and Quality Control
    - 4.4.1.1. Complementary Tests: Laboratory Tests, Diagnostic Imaging, Electrocardiogram, etc
  - 4.4.2. Evaluation of Data Obtained as a Function of Response
- 4.5. Monitoring. Trial Treatment Plan
  - 4.5.1. Monitoring Plan
  - 4.5.2. Research Timeline
  - 4.5.3. Types of Schedules
- 4.6. Main Problems in the Methodological Approaches to Treatment in the Trial
  - 4.6.1. Incorrect Documentation
  - 4.6.2. Samples
    - 4.6.2.1. Missing Samples
    - 4.6.2.2. Delayed Samples
    - 4.6.2.3. Forgotten Parameters
    - 4.6.2.4. Incorrect Sampling Times
    - 4.6.2.5. Laboratory Kit Problems
- 4.7. Specialized Methodology in Treatment I
  - 4.7.1. Clinical Trials in Veterinary Oncology
    - 4.7.1.1. Trail Phases
    - 4.7.1.2. Therapeutic Targets
    - 4.7.1.3. Biological Samples
    - 4.7.1.4. Bioequivalence
- 4.8. Specialized Methodology in Treatment II
  - 4.8.1. Clinical Trials in Veterinary Infectious Pathology I
    - 4.8.1.1. Analysis Objectives
    - 4.8.1.2. Epidemiological Clinical Trials Methodology
- 4.9. Specialized Methodology in Treatment III
  - 4.9.1. Clinical Trials in Veterinary Infectious Pathology. Prevention and Control of Veterinary Infectious Pathology II
    - 4.9.1.1. Prevention and Control of the Disease
      - 4.9.1.1.1. Institutional Strategies
    - 4.9.1.2. Risk Evaluation
- 4.10. Specialized Methodology in Treatment IV
  - 4.10.1. Clinical Trials in Veterinary Neurology
    - 4.10.1.1. Neurology Research
      - 4.10.1.1.1. Research Areas
    - 4.10.1.2. Field Work
    - 4.10.1.3. Interpreting Results

# 05 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.







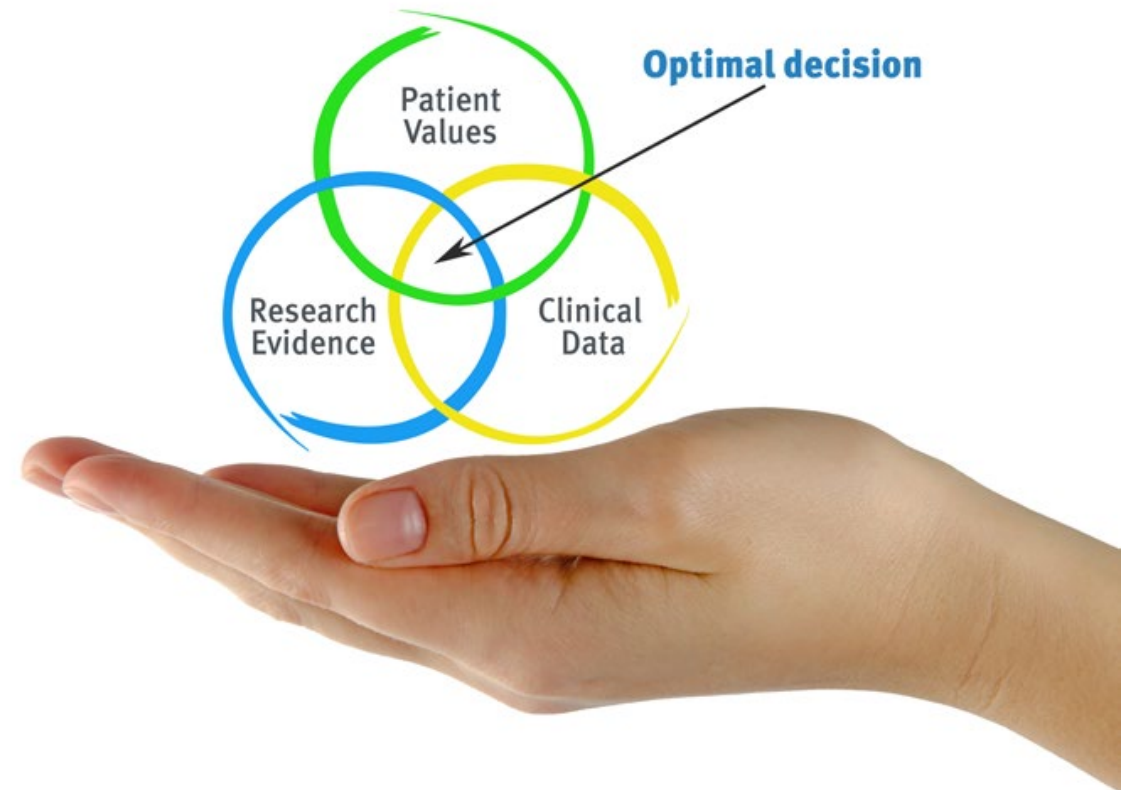
“

*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

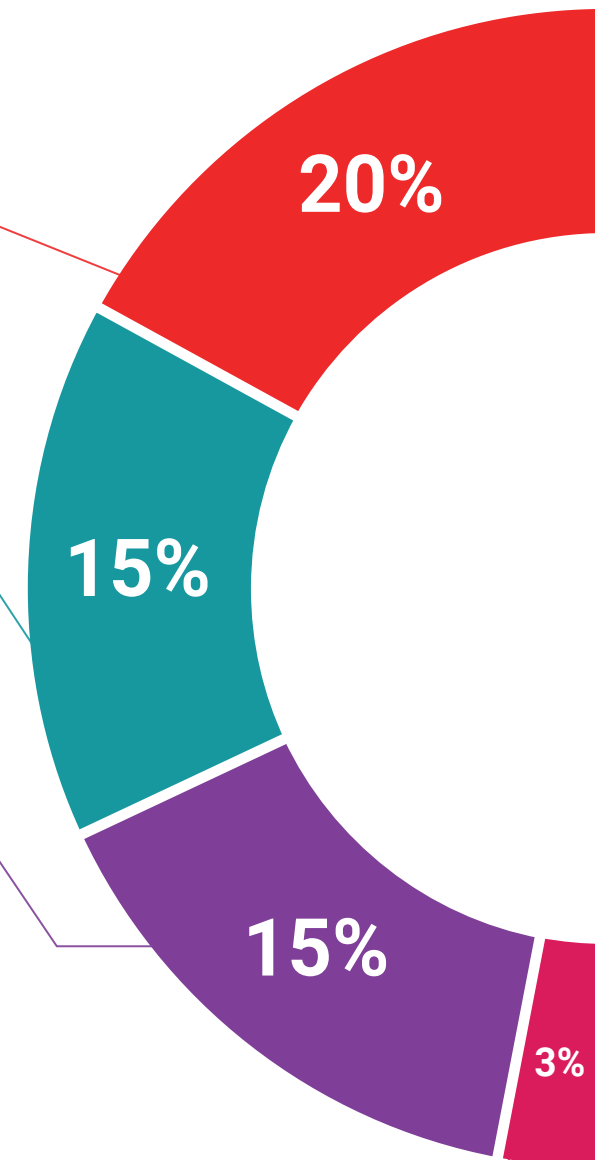
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

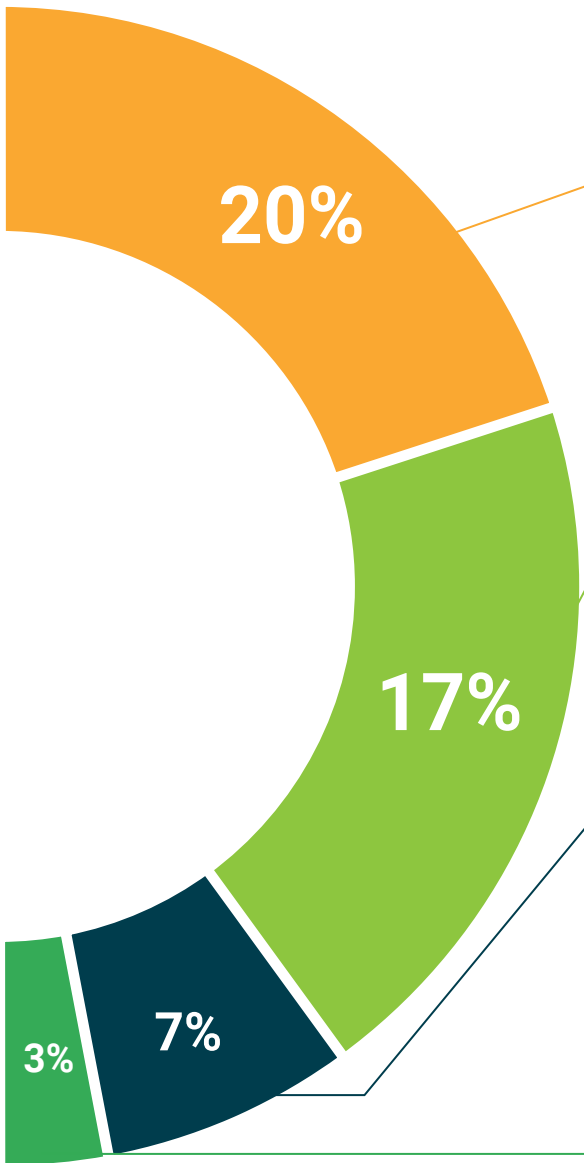
This exclusive educational system for presenting multimedia content was awarded by Microsoft as a "European Success Story".



### 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.



# 06 Certificate

The Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials guarantees, in addition to the most rigorous and up-to-date education, access to a Postgraduate Diploma issued by TECH Technological University







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*Successfully complete this program  
and receive your university degree  
without travel or laborious paperwork”*

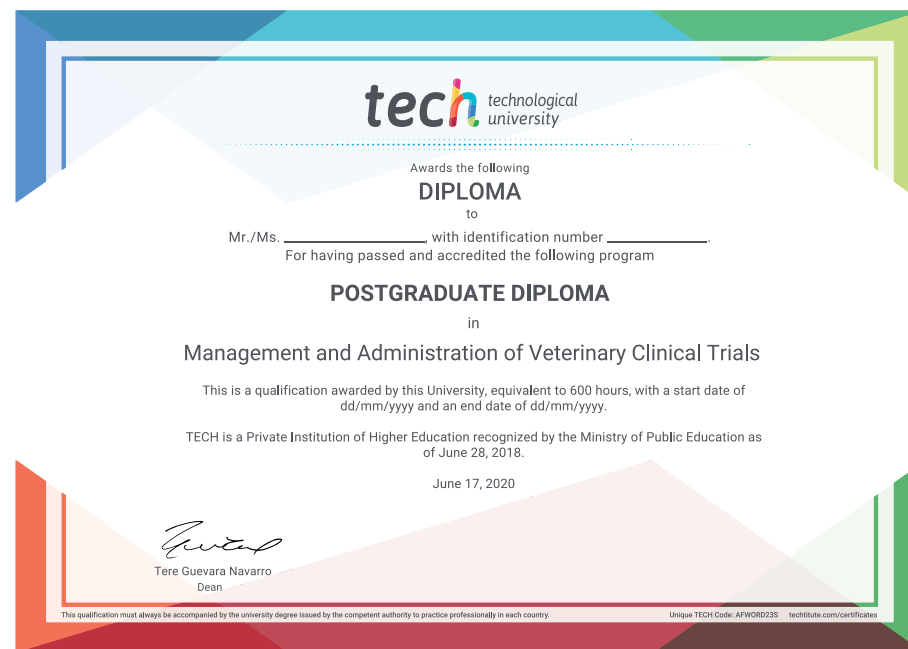
This **Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials** most complete and up to date and scientific program on the market.

After the student has passed the assessments, they will receive their corresponding **Postgraduate Diploma** issued by **TECH Technological University** via tracked delivery\*.

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

Title: **Postgraduate Diploma in Management and Administration of Veterinary Clinical Trials**

Official N° of Hours: **600 h.**



\*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.

future

health confidence people

education information tutors

guarantee accreditation teaching

institutions technology learning

community commitment

personalized service innovation

knowledge present quality

online

development languages

virtual classroom

**tech** technological  
university

## Postgraduate Diploma Management and Administration of Veterinary Clinical Trials

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

# Postgraduate Diploma

## Management and Administration of Veterinary Clinical Trials

