

# Postgraduate Diploma

Veterinary Clinical Trial Design,  
Management and Processing





## Postgraduate Diploma Veterinary Clinical Trial Design, Management and Processing

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

Website: [www.techitute.com/pk/veterinary-medicine/postgraduate-diploma/postgraduate-diploma-veterinary-clinical-trial-design-management-processing](http://www.techitute.com/pk/veterinary-medicine/postgraduate-diploma/postgraduate-diploma-veterinary-clinical-trial-design-management-processing)

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# 01

# Introduction

The Design, the methodology, the protocols to be followed, the Management, the Treatment and the evaluation are fundamental aspects in the efficiency of a Clinical Trial in Veterinary Medicine. In order to carry out these tasks with the highest quality and the best results, specific and advanced knowledge in the field is required. For this reason, TECH has designed a program that seeks to develop students' skills in this field, so that they can face their profession in this area with full capacity. In this way, a content has been designed that deals with topics such as Effectiveness Assessment, Documentation, Data Collection or Risk Assessment. All this, in a 100% online modality that gives total comfort and freedom to the student to organize their studies and schedules.



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*Become an expert in all areas of  
Veterinary Clinical Trials in a few  
months and without leaving home"*

The Design, Management and Treatment of a Clinical Trial are fundamental to guarantee the validity of the results, which will later be used as scientific evidence for decision making. Experts in this area require specific and very complete knowledge to be able to carry out their work with maximum efficiency, which is why there is an increasing demand in the labor market.

For this reason, TECH has created a Postgraduate Diploma in Veterinary Clinical Trial Design, Management and Processing, with which to enhance the knowledge and expand the skills of students in this area, so that they can stand out in their work in this area. For this purpose, the syllabus addresses topics such as Technical Documentation, Individual Selection, Contract Management, Certification, Evaluation and Specialized Methodology in Clinical Trials, among others.

All this, under a 100% online modality that gives comfort and freedom to students to organize their schedules and studies in the way that best suits them. In addition, with total availability of completely up-to-date theoretical and practical content, as well as the possibility of opening the materials from any device with an Internet connection, whether it is a tablet, computer or cell phone.

This **Postgraduate Diploma in Veterinary Clinical Trial Design, Management and Processing** contains the most complete and up-to-date scientific program on the market. Its most notable features are:

- ♦ The development of case studies presented by experts in Veterinary Clinical Trial Design, Management and Treatment
- ♦ The graphic, schematic and eminently practical contents of the book provide scientific and practical information on those 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



*Enjoy all the content from your computer, tablet or cell phone"*

“

*Test your new skills in Clinical Trials, with the most complete and dynamic practical activities"*

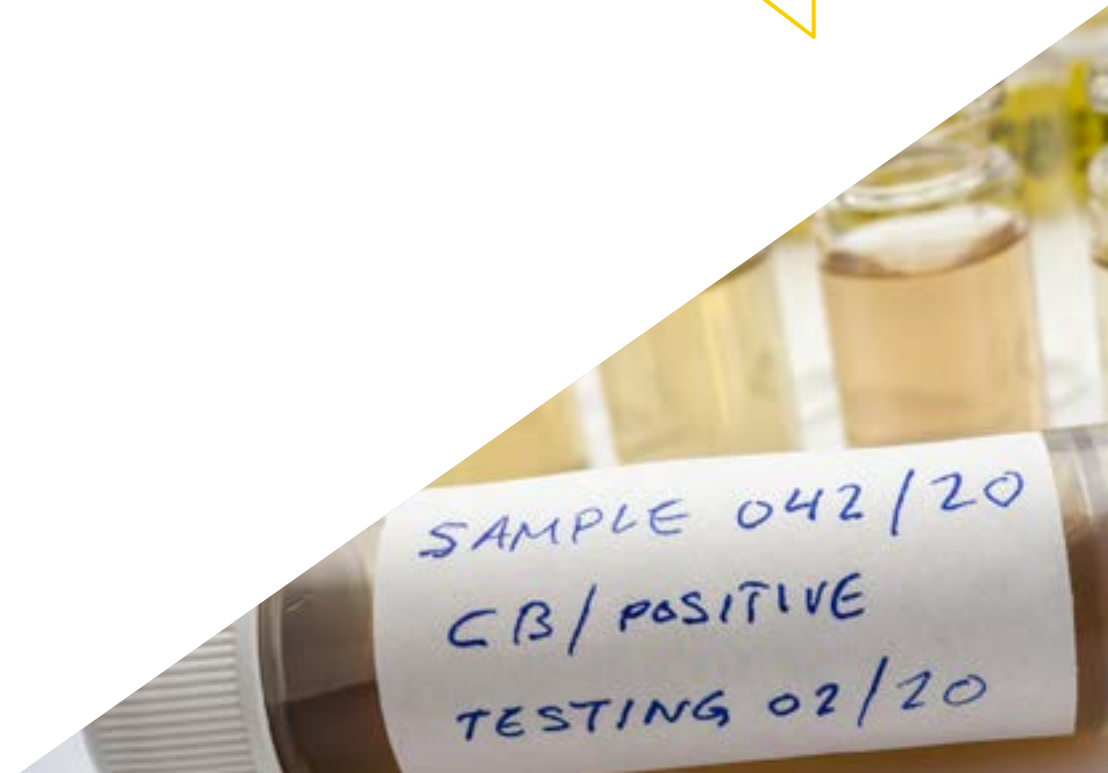
*Delves into a wealth of material on Incorrect Documentation and Specialized Methodology.*

*Acquire new knowledge in risk assessment and field work.*

The program's teaching staff includes professionals from the field who contribute their work experience to this educational 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 educational year. For this purpose, the students will be assisted by an innovative interactive video system created by renowned and experienced experts.



# 02 Objectives

The objective of this Postgraduate Diploma in Veterinary Clinical Trial Design, Management and Treatment is to provide students with the necessary skills and competencies to practice their profession with maximum efficiency and quality in the work in this sector. All this, through the most complete and innovative multimedia materials and practical exercises.





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*Learn how to master the elaboration  
of protocols for conducting Clinical  
Trials with veterinary drugs"*



## 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, toxicopharmacological 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





## Specific Objectives

### Module 1. 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 2. The Veterinary Clinical Trials II. Management, Start-ups and Commissioning

- ♦ Analyze the structure of the safety and efficacy section of a regulatory dossier
- ♦ Handle the international guidelines on the conduct of safety studies in veterinary medicine (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 3. The Veterinary Clinical Trials III. 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

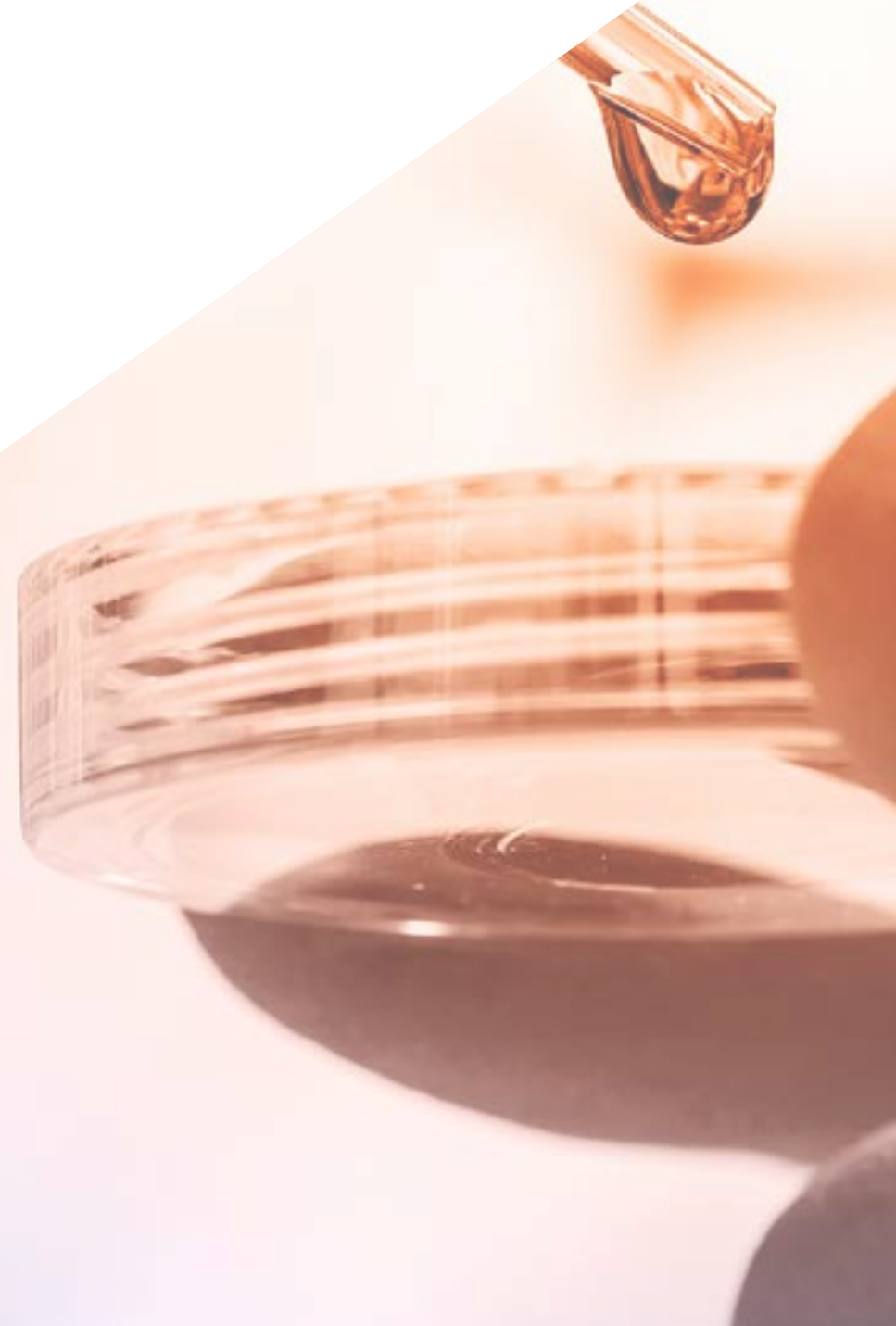


*Reach your most demanding goals  
in the field of Clinical Trials and  
stand out in a booming sector"*

03

# Course Management

The management and teachers of this syllabus have been selected under the highest quality standards TECH is accustomed to working with. In this way, the best professionals have been chosen, forming a team of experts to meet the most demanding expectations.



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*Solve your doubts and expand your knowledge with the constant support of TECH's team of experts in Clinical Trials"*

## Management



### Dr. Martín Palomino, Pedro

- Manager of ALJIBE Veterinary Laboratory
- Senior program researcher at the Castilla-La Mancha Research Center Spain. BORRAR
- 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

### Mr. Pacheco Bermejo, Cristian

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

### Dr. 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

### 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 Veterinary Drug Efficacy Area
- ♦ Pharmacological studies at 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 European University

# 04

## Structure and Content

TECH has selected the most distinguished experts in Clinical Trials to bring their experience and specialized knowledge to the syllabus, resulting in a complete and up-to-date program that represents a unique opportunity in the academic market. Moreover, always based on the most efficient pedagogical methodology, Relearning, in which TECH is a pioneer and which guarantees the natural and progressive assimilation of the essential concepts by the students.



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*TECH Relearning guarantees optimal assimilation of essential concepts, without the need to dedicate excessive time to study”*

## Module 1. The Veterinary Clinical Trial I. Design and Methodology

- 1.1. Veterinary Clinical Trials
  - 1.1.1. Veterinary Clinical Trial Research
  - 1.1.2. Conditions for Conducting a Veterinary Clinical Trial Investigation
  - 1.1.3. Types of Veterinary Clinical Trials
    - 1.1.3.1. Types of Trials According to the Study Design
    - 1.1.3.2. Parallelisms
    - 1.1.3.3. Crusader
    - 1.1.3.4. In Pairs
    - 1.1.3.5. Sequentials
- 1.2. Data Collection Notebooks
- 1.3. Identification of Information Sources for a Veterinary Clinical Trial
  - 1.3.1. How To Find Information We Are Interested In
    - 1.3.1.1. Choice of Source
    - 1.3.1.2. Resources and Access Modes
    - 1.3.1.3. How to Search for the Best Evidence on a Topic
- 1.4. Elaboration of a Protocol for the Conduct of a Clinical Trial with Veterinary Medication
  - 1.4.1. General Information
  - 1.4.2. Justification and Objectives
  - 1.4.3. Test Outline
- 1.5. Design of the Veterinary Clinical Trials
  - 1.5.1. Individual Selection
  - 1.5.2. Inclusion/Exclusion Criteria
  - 1.5.3. Treatment
  - 1.5.4. Destination of Study Animals, Products Derived from Study Animals and Products under Clinical Investigation and Control Products
  - 1.5.5. Adverse Events (AEs)
- 1.6. Methodology in Veterinary Clinical Trial Research
  - 1.6.1. Hypotheses
  - 1.6.2. Randomization
  - 1.6.3. City
  - 1.6.4. Sampling
  - 1.6.5. Uncontrolled Trials
  - 1.6.6. Controlled Trials
    - 1.6.6.1. Open
    - 1.6.6.2. Blind
    - 1.6.6.3. Double-Blind
    - 1.6.6.4. Triple-Blind
    - 1.6.6.5. Pilot
- 1.7. Methodological Procedures in a Veterinary Clinical Trial (VCT)
  - 1.7.1. Discrimination Between CD in Humans and Animals
  - 1.7.2. Differences
  - 1.7.3. Implementation
  - 1.7.4. External and Internal Validity
  - 1.7.5. Variables
  - 1.7.6. Consent
  - 1.7.7. Reproducibility
  - 1.7.8. Risk
- 1.8. Evaluation of the Efficiency of the Veterinary Clinical Trial.
  - 1.8.1. Statistics
  - 1.8.2. Records Management
  - 1.8.3. Annexes Attached to Protocol
  - 1.8.4. Changes in Protocol
  - 1.8.5. References
- 1.9. Research Quality in a Veterinary Clinical Trial
  - 1.9.1. Legal Aspects
  - 1.9.2. Scientific Aspects
  - 1.9.3. Risk-Benefit Assessment
- 1.10. Ethical Principles in a Veterinary Clinical Trial
  - 1.10.1. Historical Background
  - 1.10.2. Ethical Codes
  - 1.10.3. Application of Ethical Principles



## Module 2. The Veterinary Clinical Trials II. Management, Start-ups and Commissioning

- 2.1. Clinical Trial Management Preclinical Development
  - 2.1.1. Preclinical Development
    - 2.1.1.1. Animal Experimentation Committees
  - 2.1.2. Exploratory Clinical Trial
  - 2.1.3. Regulatory Clinical Trial
- 2.2. Clinical Trial Authorization Process
  - 2.2.1. Application for a Product in Veterinary Research
  - 2.2.2. Request for a Veterinary Clinical Trial
- 2.3. Documents at the Beginning of the Clinical Trial
  - 2.3.1. Contract Management
  - 2.3.2. Clinical Trial Protocol
  - 2.3.3. Informed Consent
- 2.4. Clinical Trial Initiation and Start-Up
  - 2.4.1. Initial Visit and Center Opening
  - 2.4.2. Data Collection Notebooks (DCNs)
  - 2.4.3. Electronic Data Collection (EDC)
- 2.5. }Documentary Archive of a Clinical Trial
  - 2.5.1. Medication Shipment and Management
  - 2.5.2. Documentation Custody
- 2.6. Final Report
  - 2.6.1. Center Closures
  - 2.6.2. Clinical Trial Documentation Audit
  - 2.6.3. Audit of Data Management Activities
- 2.7. Laboratory Certification
  - 2.7.1. Laboratory Certification: GMP
  - 2.7.2. Laboratory Certification: GLP
  - 2.7.3. Laboratory Certification: ISO
- 2.8. Regulatory Dossier Structure
  - 2.8.1. Document Management
  - 2.8.2. Validation of the Internal Structure
  - 2.8.3. Electronic Communication with Regulatory Agencies

- 2.9. Writing Results
  - 2.9.1. Publication of Clinical Trials in Scientific Journals
- 2.10. CONSORT Recommendations

### Module 3. The Veterinary Clinical Trials III. Trial Treatment

- 3.1. Description of Trail Treatment
  - 3.1.1. What Does the Dose Description, Interval, Route and Form of Administration and Duration of the Treatment to be Trialed Depend on?
  - 3.1.2. Criteria for the Creation of Patterns Throughout the Trial
- 3.2. Application of Special Rules to the Trail Treatment
  - 3.2.1. Situations for Application of Special Rules to Trail Treatment
  - 3.2.2. Measures to Assess Therapeutic Compliance in Special Situations
    - 3.2.2.1. Examples of Special Situations
- 3.3. Treatment Response
  - 3.3.1. Data Collection
- 3.4. Methods and Evaluation of Treatment Response
  - 3.4.1. Description of the Methods Used for Response Assessment and Quality Control
    - 3.4.1.1. Complementary Tests: Laboratory Tests, Diagnostic Imaging, Electrocardiogram, etc.
  - 3.4.2. Evaluation of Data Obtained as a Function of Response
- 3.5. Monitoring. Trial Treatment Plan
  - 3.5.1. Monitoring Plan
  - 3.5.2. Research Timeline
  - 3.5.3. Types of Schedules
- 3.6. Main Problems in the Methodological Approaches to Treatment in the Trial
  - 3.6.1. Incorrect Documentation
  - 3.6.2. Samples
    - 3.6.2.1. Missing Samples
    - 3.6.2.2. Delayed Samples
    - 3.6.2.3. Forgotten Parameters
    - 3.6.2.4. Incorrect Sampling Times
    - 3.6.2.5. Laboratory Kit Problems





- 3.7. Specialized Methodology in Treatment I
  - 3.7.1. Clinical Trials in Veterinary Oncology
    - 3.7.1.1. Trail Phases
    - 3.7.1.2. Therapeutic Targets
    - 3.7.1.3. Biological Samples
    - 3.7.1.4. Bioequivalence
- 3.8. Specialized Methodology in Treatment II
  - 3.8.1. Clinical Trials in Veterinary Infectious Pathology I
    - 3.8.1.1. Analysis Objectives
    - 3.8.1.2. Epidemiological Clinical Trials Methodology
- 3.9. Specialized Methodology in Treatment III
  - 3.9.1. Clinical Trials in Veterinary Infectious Pathology. Prevention and Control of Veterinary Infectious Pathology II
    - 3.9.1.1. Prevention and Control of the Disease
      - 3.9.1.1.1. Institutional Strategies
    - 3.9.1.2. Risk Assessment
- 3.10. Specialized Methodology in Treatment IV
  - 3.10.1. Clinical Trials in Veterinary Neurology
    - 3.10.1.1. Neurology Research
      - 3.10.1.1.1. Research Areas
    - 3.10.1.2. Field Work
    - 3.10.1.3. Interpreting Results



*Enroll now and get a professional position in one of the most promising areas in the veterinary field"*

# 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. Gervas, 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.

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*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

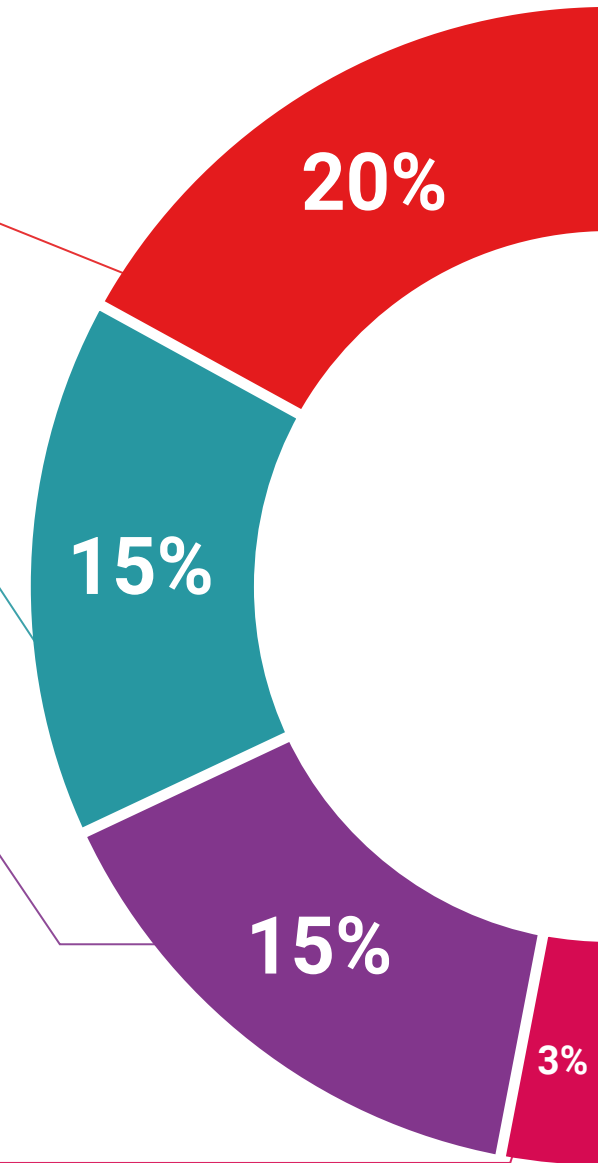
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

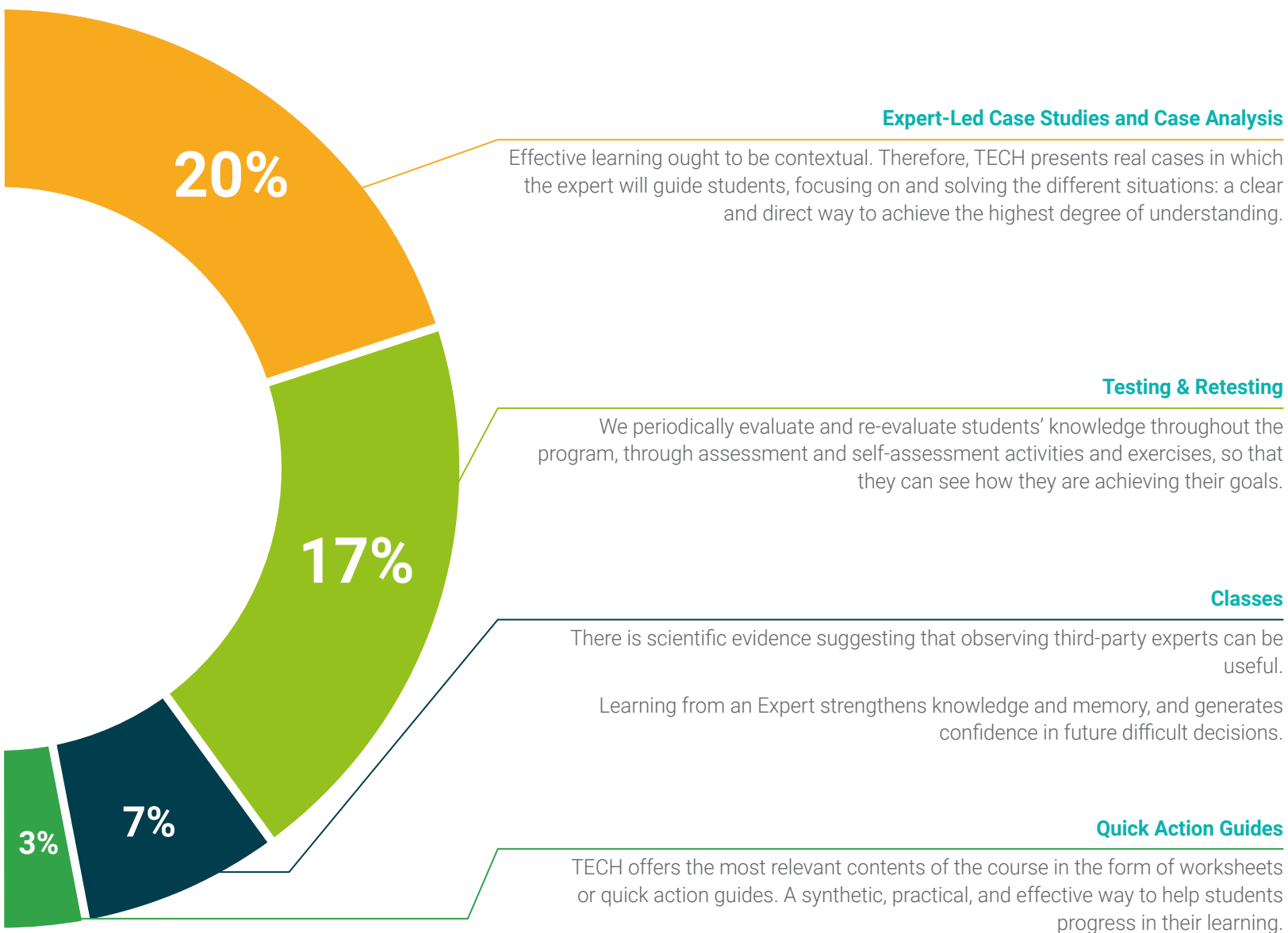
This exclusive educational system for presenting multimedia content was awarded by Microsoft as a "European Success Story".



#### 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.





# 06 Certificate

The Postgraduate Diploma in Veterinary Clinical Trial Design, Management and Processing guarantees students, 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 qualification without  
having to travel or fill out laborious paperwork”*

This **Postgraduate Diploma in Veterinary Clinical Trial Design, Management and Processing** contains the most complete and up-to-date scientific 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 certificate 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 Veterinary Clinical Trial Design, Management and Processing**

Official N° of Hours: **600 h.**



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



## Postgraduate Diploma

### Veterinary Clinical Trial Design, Management and Processing

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

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## Veterinary Clinical Trial Design, Management and Processing

