Postgraduate Diploma

Design, Methodology and Legislation

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Postgraduate Diploma
Design, Methodology and Legislation

- Modality: **online**
- Duration: **6 months**
- Certificate: **TECH Global University**
- Accreditation: **24 ECTS**
- Schedule: **at your own pace**
- Exams: **online**

Website: www.techtitute.com/us/veterinary-medicine/postgraduate-diploma/postgraduate-diploma-design-methodology-legislation

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01

Introduction

Within the field of clinical trials, the design, the applicable regulatory framework and the development of its methodology are very relevant factors that require specific and advanced knowledge. This is the reason why TECH has designed a program that seeks to meet the demand for professionals with skills and competencies in this area, who know how to carry out their work with the maximum possible efficiency. For this purpose, this study plan goes in depth into topics such as Legislation and Regulations Applicable to Clinical Trials, Sources of Information, Design or Methodological Procedures, among others. All this, in a comfortable 100% online modality and with the most practical and complete pedagogical materials of the academic market.

Become an expert in the field of Design, Methodology and Legislation in Veterinary Clinical Trials in a few months"

Design, Methodology and Legislation are essential aspects to guarantee the validity of the results, which will be used as scientific evidence to support therapeutic decision-making in practice and to endorse the registration of a drug for marketing. This is why professionals with specific and advanced knowledge in these areas are increasingly in demand in the labor market.

For this reason, TECH has designed a Postgraduate Diploma in Design, Methodology and Legislation, so that students can acquire the necessary skills and competencies to be able to work in this area of veterinary medicine, with maximum efficiency in their work. And this, through the exploration of topics such as Laboratory Certification, Quality in Research, Identification of Information Sources, Technical Documentation or the Legislation and Regulations Applicable in Veterinary Clinical Trials, among many other relevant aspects.

All this, in a comfortable 100% online mode that gives total freedom to the student to organize their studies and schedules, without the need to travel, or seeing altered their daily work. In addition, the most updated multimedia contents, the most complete information and the latest teaching tools are available.

This **Postgraduate Diploma in Design, Methodology and Legislation** contains the most complete and up-to-date scientific program on the market. The most important features include:

- The development of practical cases presented by experts in Design, Methodology and Legislation
- The graphic, schematic and eminently practical contents with which it is conceived gather scientific and practical information on those disciplines that are indispensable 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

Reach your maximum potential in just a few months and stand out in one of the most promising areas of the veterinary labor market"

Access all the content available in the Virtual Campus on Management, Start-up and Implementation of Clinical Trials"

Access the most exhaustive information on Legislation and European regulations.

Improve your skills in Methodological Procedures and Veterinary Clinical Trial Design.

The program's teaching staff includes professionals from the sector who contribute their work experience to this specializing 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.

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, 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 Design, Methodology and Legislation is to provide students with the necessary skills to be able to carry out their work in this professional area with the highest quality in their work. All this, through the most complete and dynamic content in the academic market.

Register now and get access to the best content on Clinical Trials Legislation"

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

Specific Objectives

Module 1. 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 2. Veterinary Clinical Trials 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. Veterinary Clinical Trials II. Management, Initiation and Implementation

- 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

A unique academic opportunity to delve into Assessment of the Effectiveness of Veterinary Clinical Trials"

03

Course Management

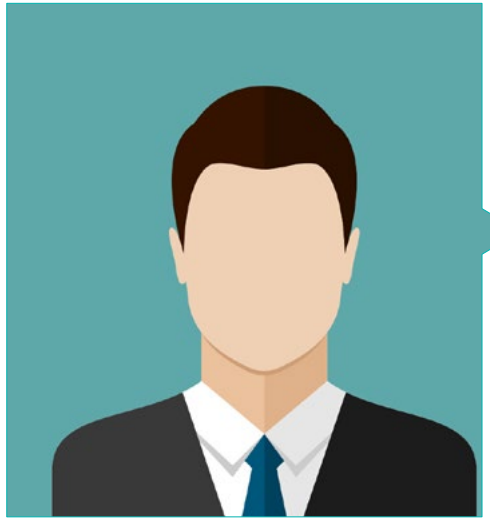
The management and teaching staff of this curriculum have been selected by TECH, under the highest standards and in the pursuit of excellence in teaching that characterizes it so much. In this way, the best professionals of its team, experts in Veterinary Clinical Trials, have been chosen, and they have contributed their experience and more specific knowledge in all the content.

During the program, you will be able to solve any doubt or query thanks to the constant support of TECH's excellent team of experts"

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. Espigares Espigares, David

- Head of Swine Technical Service at Ceva Salud Animal. Spain
- Veterinary Clinical Trials Specialist
- Veterinarian in Provesa
- Veterinarian in Bibiano y Cia, S.L.
- Collaborating Researcher in the Animal Breeding and Health Research Group
- Collaborator in postgraduate studies
- Secretary of AVEPOMUR (Association of Swine Veterinarians of the Region of Murcia)
- Degree in Veterinary Medicine from the University of Murcia
- Master's Degree in Pharmaceutical Marketing from the National University of Remote Education (UNED)
- Master's Degree in Integral Management of in Veterinary Clinical Trials by Universidad Europea of Madrid

Mr. Pacheco Bermejo, Cristian

- Clinical Trials Nurse Specialist
- Nurse at Fresenius Medical Care Clinic Cáceres, Spain
- Emergency Department Nurse at the University Hospital San Pedro de Alcántara 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. Serrano García, Alicia

- Specialist in Applied Ethology and Marine Mammals
- Caretaker of marine mammals at the Zoo Aquarium of Madrid
- Caretaker of marine mammals in Mundomar Benidorm
- Curricular internship with marine mammals at Oceanographic de Valencia
- PhD in Applied Ethology from the Autonomous University of Madrid.
- Graduate in Biology from the Rey Juan Carlos University of Madrid
- Specialist in marine mammals by Sea Wolves
- Master's Degree in Applied Ethology from the Autonomous University of Madrid
- Courses in Monographs by Zoo Aquarium of Madrid

04

Structure and Content

The content and structure of this program have been designed by the outstanding professionals that make up TECH's team of experts, who have poured their experience and their best skills into all the material. All this, based on the most efficient pedagogical methodology, Relearning, which guarantees an optimal assimilation of the contents by the students, in a natural, precise and dynamic way.

Thanks to the pedagogical methodology of TECH Relearning, you will be able to acquire new knowledge without the need to spend too much time studying"

Module 1. Legislation Applicable to Veterinary Clinical Trials

1.1. European Medicines Agency (EMA)

1.2. European Legislation and Regulations Applicable to Medicinal Products and Veterinary Clinical Trials I

- 1.2.1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Drugs

1.3. European Legislation and Regulations Applicable to Veterinary Drugs and Clinical Trials II

- 1.3.1. Maximum Residue Limits

1.4. International Conference on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products. VICH Program

1.5. Veterinary Drug Registration Procedures

- 1.5.1. Centralized, Mutual Recognition and Decentralized Procedure

Module 2. Veterinary Clinical Trials 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. Cross-Over Transplantation
  - 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)

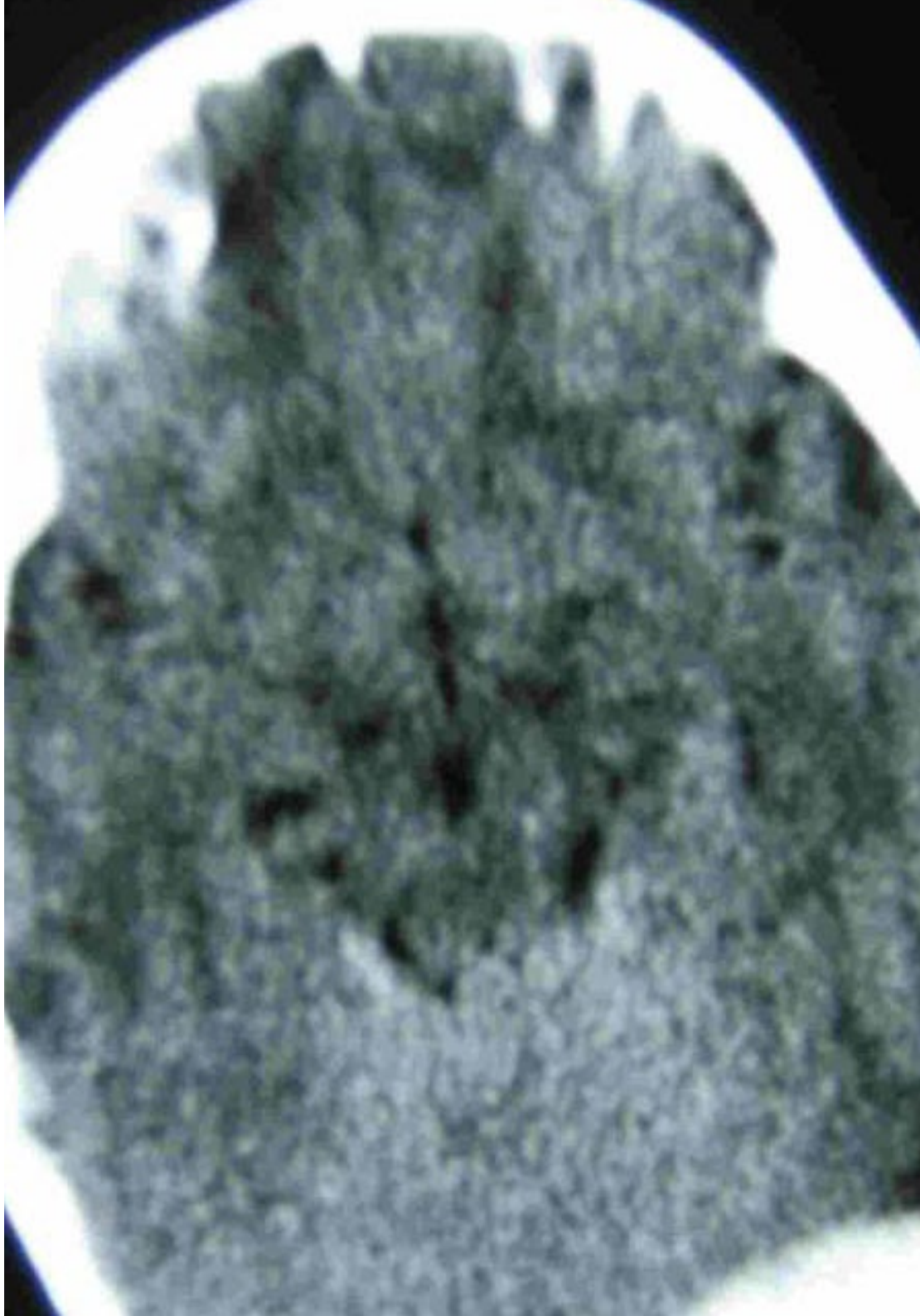
2.5. Methodology in Veterinary Clinical Trial Research
- 2.5.1. Hypotheses
- 2.5.2. Randomization
- 2.5.3. City
- 2.5.4. Sampling
- 2.5.5. Uncontrolled Trials
- 2.5.6. Controlled Trials
  - 2.5.6.1. Open
  - 2.5.6.2. Blind
  - 2.5.6.3. Double-Blind
  - 2.5.6.4. Triple-Blind
  - 2.5.6.5. Pilot

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. Veterinary Clinical Trials II. Management, Initiation and Implementation

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

3.4. Clinical Trial Initiation and Implementation
- 3.4.1. Initial Visit and Center Opening
- 3.4.2. Data Collection Notebooks (DCNs)
- 3.4.3. Electronic Data Capture (EDC)

3.5. Clinical Trial Documentation Archive
- 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. Writing Results
- 3.9.1. Publication of Clinical Trials in Scientific Journals

3.10. CONSORT Recommendations

Opt for a program that will allow you to get up to date on the latest trends in Design, Methodology and Legislation in Veterinary Clinical Trials"

05

Methodology

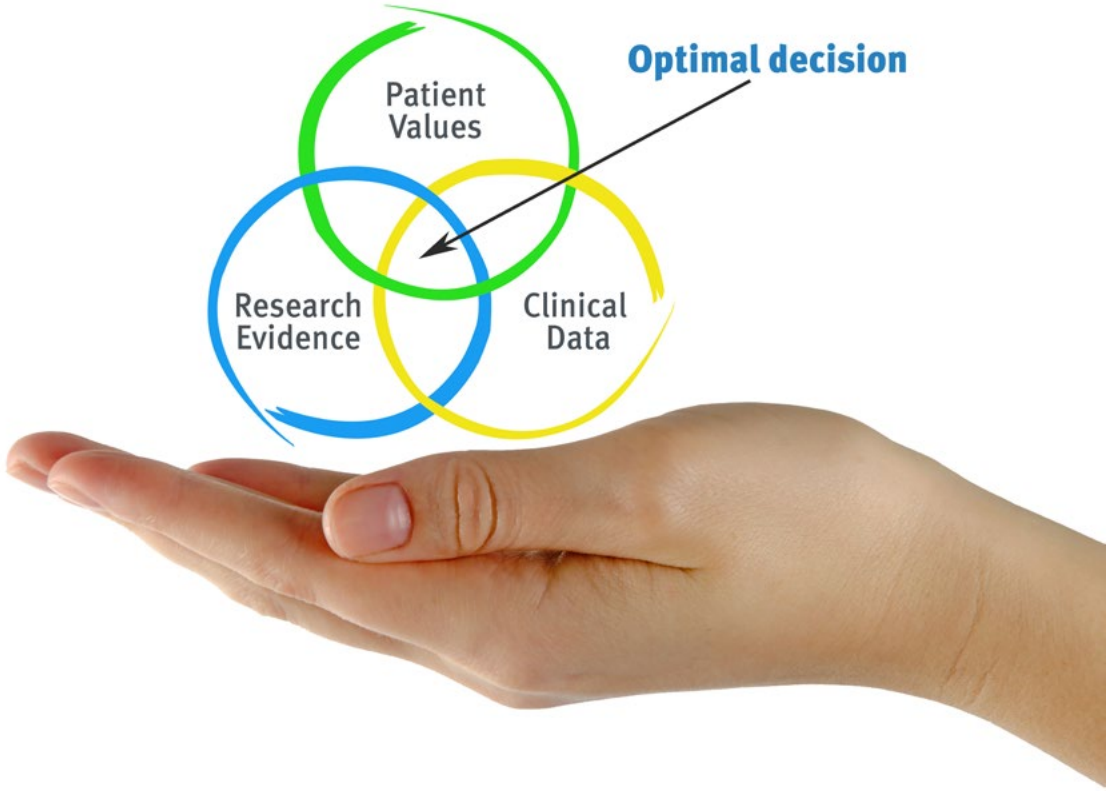
This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning.**
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine**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

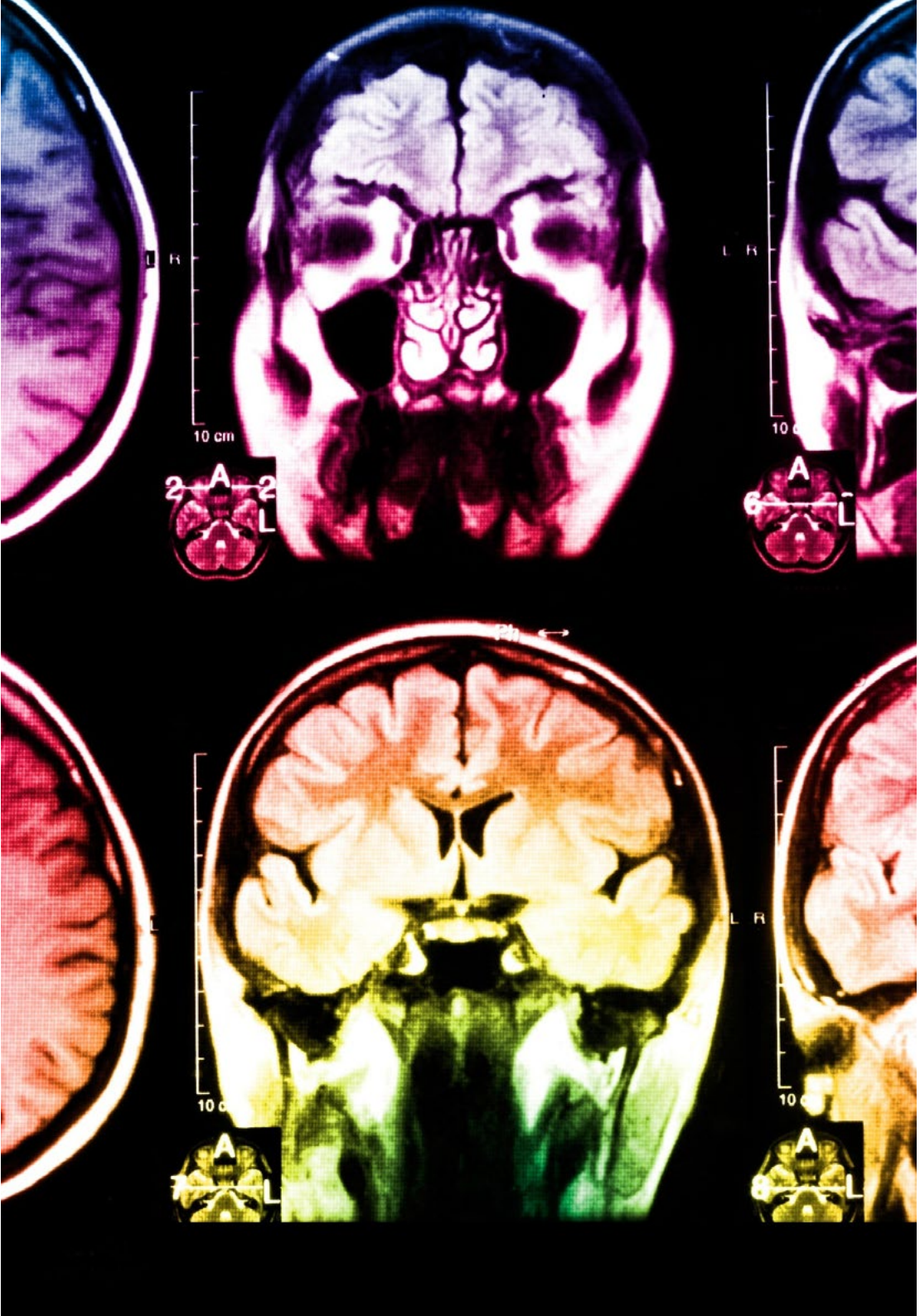
1. Veterinarians who follow this method not only manage to assimilate concepts, but also develop their mental capacity through exercises to evaluate real situations and knowledge application
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real 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.

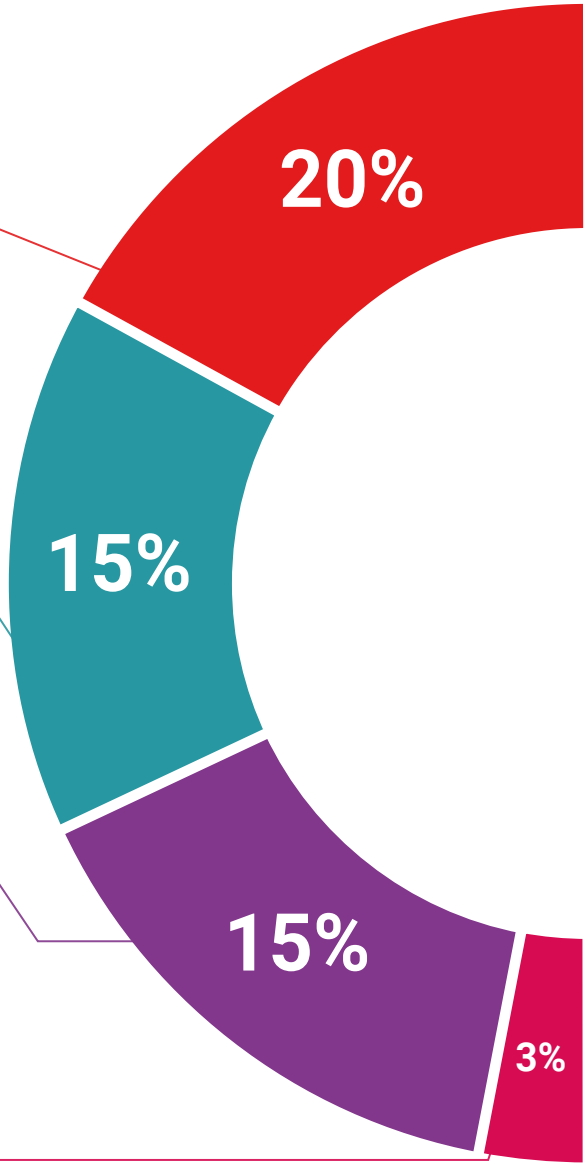
Interactive Summaries

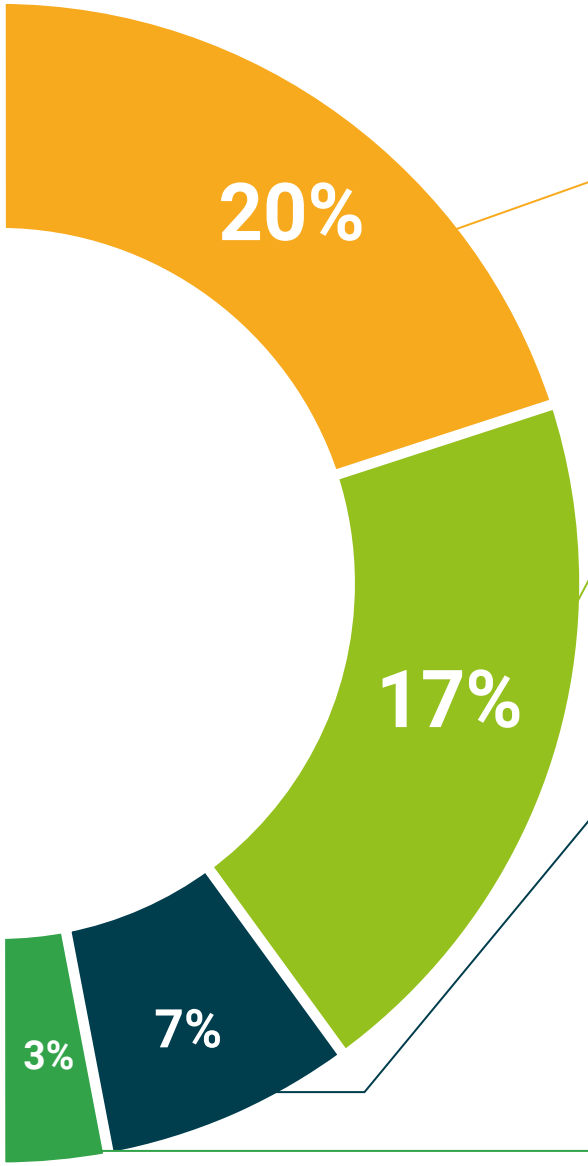
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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

This Postgraduate Diploma in Design, Methodology and Legislation guarantees, in addition to the most rigorous and up to date education, access to a Postgraduate Diploma issued by TECH Global University.

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

This private qualification will allow you to obtain a **Postgraduate Diploma in Design, Methodology and Legislation** endorsed by **TECH Global University**, the world's largest online university.

TECH Global University is an official European University publicly recognized by the Government of Andorra (***official bulletin***). Andorra is part of the European Higher Education Area (EHEA) since 2003. The EHEA is an initiative promoted by the European Union that aims to organize the international training framework and harmonize the higher education systems of the member countries of this space. The project promotes common values, the implementation of collaborative tools and strengthening its quality assurance mechanisms to enhance collaboration and mobility among students, researchers and academics.

This **TECH Global University** private qualification is a European program of continuing education and professional updating that guarantees the acquisition of competencies in its area of knowledge, providing a high curricular value to the student who completes the program.

Title: **Postgraduate Diploma in Design, Methodology and Legislation**

Modality: **Online**

Duration: **6 months.**

Accreditation: **24 ECTS**


tech global university

Mr./Ms. _____, with identification document _____
has successfully passed and obtained the title of:

Postgraduate Diploma in Design, Methodology and Legislation

This is a private qualification of 720 hours of duration equivalent to 24 ECTS, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH Global University is a university officially recognized by the Government of Andorra on the 31st of January of 2024, which belongs to the European Higher Education Area (EHEA).

In Andorra la Vella, on the 28th of February of 2024

Dr. Pedro Navarro Illana
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

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

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