



Postgraduate Certificate

Clinical Trials, Principal Investigator, Monitor and Sponsor

» Modality: online

» Duration: 12 weeks

» Certificate: TECH Technological University

» Dedication: 16h/week

» Schedule: at your own pace

» Exams: online

Website: www.techtitute.com/us/veterinary-medicine/postgraduate-certificate/clinical-trials-principal-investigator-monitor-sponsor

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tech 06 | Introduction

In a Clinical Trial there are different figures that form a relevant part of the process, in addition to the Principal Investigator. The Sponsor who is in charge of bringing together the specialists who will carry out the study, as well as the Monitor, who is the link between this team and what is usually a development company, stand out. These professions are constantly on the rise and require in-depth and advanced specialization.

For this reason, TECH has designed a Postgraduate Certificate in Clinical Trials, Principal Investigator, Monitor and Sponsor, to provide students with the necessary skills and competencies to address these functions with total efficiency and specific knowledge. In this way, the contents delve into topics such as Study Design, Evidence-Based Veterinary Medicine, Ethical and Legal Regulations, the Research Team and Quality Control or Sponsors of Clinical Trials, among many other topics.

All this, in a comfortable 100% online mode that gives the student total freedom to organize their studies and schedules, without limitations of any kind. In addition, you can count on the most complete and up-to-date theoretical and practical content on the educational market, accessible from any device with an Internet connection.

This Postgraduate Certificate in Clinical Trials, Principal Investigator, Monitor and Sponsor 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 Clinical Trial Principal Investigator, Monitor and Sponsor
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- Practical exercises where self-assessment can be used to improve learning
- Its special emphasis on innovative methodologies
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- Content that is accessible from any fixed or portable device with an Internet connection



Train your skills as a Monitor or Sponsor and achieve a promising future in one of the most promising areas in the veterinary field"



Thanks to its 100% online modality, the content will be available on the Virtual Campus from the beginning of the course, so you can enjoy it whenever you want"

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

Its multimedia content, developed with the latest educational technology, will allow the professional a situated and contextual learning, that is, a simulated environment that will provide an immersive training programmed to train in real situations.

The design of this program focuses on Problem-Based Learning, in which the professional will have to try to solve the different professional practice situations that will arise throughout the academic course. This will be done with the help of an innovative system of interactive videos made by renowned experts.

You will have all the information you need to delve into Protocols, Reports and Investigator Interaction.

A program designed to help you achieve professional excellence in the veterinary environment.







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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

- 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
- Determine the role of each participant in the veterinary Clinical Trials research process, both in general and of the veterinarian in particular
- Establish different roles in the research process and control of results
- Examine factors and elements of the skills of actors in the testing process
- Analyze the actions that guide the Clinical Trial process
- Manage projects and Clinical Trials in scientific, technical and monitoring contexts
- Determine the role and interests of the different stakeholders required
- Analyze recruitment strategies for companies and researchers

- Audit the research process and detect events of relevance to the progress of the research process
- Issue partial, event and final reports
- Decide on study sites and their monitoring
- Ensure controls regarding data quality
- Manage applicable legislation



03 Course Management

The teaching staff and management of this Postgraduate Certificate in Clinical Trials, Principal Investigator, Monitor and Sponsor are made up of prestigious professionals who are part of TECH's team of experts. They have shaped the content, thanks to their extensive and outstanding backgrounds, generating teaching materials of the highest possible quality.



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







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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. The Research Ouestion
 - 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

- I.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. The Research Question
 - 1.4.1. Origins of Research Questions
 - 1.4.1.1. Research Ouestion in Literature
 - 1.4.1.2. New Ideas and Techniques
 - 1.4.1.3. Choosing a Mentor
 - 1.4.2. Good Research Ouestion 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



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1.5.	Sample	Size	Calculation

- 1.5.1. Hypotheses
- 1.5.2. Hypotheses Types
 - 1.5.2.1. Null and Alternative Hypothesis
 - 1.5.2.2. One-Sided and Two-Sided Alternative Hypotheses
- 1.5.3. Statistical Principles
 - 1.5.3.1. Type I and II Errors
 - 1.5.3.2. Effect Size
 - 1.5.3.3. Alpha (α) and Beta (β)
 - 1.5.3.4. Probability Value (p)
 - 1.5.3.5. Types of Statistical Tests
- 1.5.4. Additional Concepts
 - 1.5.4.1. Variability
 - 1.5.4.2. Multiple and Post Hoc Hypotheses
 - 1.5.4.3. Primary and Secondary Hypotheses
- 1.5.5. Summary
- 1.6. Bibliographic Search: Access to Scientific Information
 - 1.6.1. What is Scientific Information: How Is It Presented?
 - 1.6.2. What Do We Need It For and What Should We Do With It?
 - 1.6.3. Types of Questions
 - 1.6.4. Preparing for the Search: Before, During and After
 - 1.6.5. Where to Look Data Bases
 - 1.6.6. What Do We Need to Consult Databases? Interrogation Languages and Keywords
 - 1.6.7. Thesauri in Health Sciences
 - 1.6.8. PubMed
 - 1.6.8.1. Introduction
 - 1.6.8.2. Simple Search. MESH Descriptors. Advanced Search
 - 1.6.8.3. Filters
 - 1.6.8.4. Results
 - 1.6.9. Where and How to Locate Evidence
 - 1.6.9.1. Introduction
 - 1.6.9.2. Pyramids of Evidence and Information Sources

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1.7.

	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	
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

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1.8.	Animal	Testina
1.0.	Allilliai	ICOLLING

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 Principal Investigator, Sponsor and Monitor of Veterinary Clinical Trials (VCT)

- 2.1. Professional Approach to Clinical Trials
 - 2.1.1. Business, Science and Clinical Trials
 - 2.1.1.1. Clinical Trials in the Public and Private Sector
 - 2.1.1.2. Public-Private Preliminary Interaction
- 2.2. Veterinary Profession in the Context of Clinical Trials
 - 2.2.1. Adequacy of the Veterinary Profession in Clinical Trials
 - 2.2.2. Reasons for Conducting Clinical Trials
 - 2.2.3. Registration and Animal Protection in Veterinary Clinical Trials
 - 2.2.4. Follow-Up Veterinary Care
- 2.3. Principal Investigator's Guide
 - 2.3.1. Researchers and Companies Technical Assistance Companies
 - 2.3.1.1. Search Resources for Public and Private Companies
 - 2.3.1.2. Budget Preparation Models

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2.3.2.	Respo	onsibilities	and Regu	ulatory	Committees

- 2.3.2.1. Responsibilities of Technical Assistance Centers
- 2.3.2.2. PI Responsibilities
- 2.3.2.3. Other Participants with Responsibilities
- 2.3.2.4. Institutional Animal Protection and Welfare Committee
- 2.3.3. Budget Development and Negotiation
 - 2.3.3.1. Sponsors and their Types
 - 2.3.3.2. Role of the Principal Investigator
 - 2.3.3.3. Study Activation and Preliminary Reports
- 2.4. The Research Equipment in Veterinary Clinical Trials I
 - 2.4.1. Research Equipment and Data Management
 - 2.4.1.1. Principal Investigator
 - 2.4.1.2. Other Research Participants
 - 2.4.1.3. Clinical Trial Subjects
 - 2.4.1.4. Databases. Management and Administration
- 2.5. The Research Team and Data Quality Control II
 - 2.5.1. Data Sources
 - 2.5.2. Choice of Database from Collection and Archiving System
 - 2.5.3. Data Quality Control
 - 2.5.4. Data Security Monitoring and Audits
- 2.6. Good Clinical Practices, Protocol Agreement and Participant Evaluation
 - 2.6.1. Guarantees of Research Integrity and Protection of Participant's Security
 - 2.6.2. Timing of Data Management Plans
 - 2.6.3. Management of Research Personnel and Resources in Context
 - 2.6.4. Automated Systems
- 2.7. The Principal Investigator (PI) in the Veterinary Clinical Trial
 - 2.7.1. Administration and Financial Management of the Sponsored Program
 - 2.7.2. Conflicts of Interest
 - 2.7.3. Research Participant Protection
 - 2.7.4. Environmental Health and Safety
 - 2.7.5. Patents and Inventions
 - 2.7.6. Export Controls





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- 2.8. Veterinary Population Involved in Biomedical Research
 - 2.8.1. Veterinary Population Involved in Biomedical Research
 - 2.8.2. Relevant Activity Areas
 - 2.8.3. Professional Merits
- 2.9. Sponsors of Veterinary Clinical Trials
 - 2.9.1. Private Sector
 - 2.9.2. Foundations
 - 2.9.3. Other Promotion Sources
- 2.10. The Monitor: Training and Primary Function
 - 2.10.1. Monitor Training and Designation
 - 2.10.1.1. Preparation, Attitude and Qualification
 - 2.10.1.2. Sponsors
 - 2.10.2. Reporting Protocols and Forms
 - 2.10.2.1. Protocol Reviews
 - 2.10.2.2. Case Report Forms
 - 2.10.2.3. Final Study Reports (According to VICH GL9 Competencies)
 - 2.10.3. Interaction with Researchers, Laboratories and Laboratory Personnel
 - 2.10.3.1. IP Selection
 - 2.10.3.2. Laboratory Selection
 - 2.10.3.3. Location Selection



Bet on your future and get to know in depth the figures of Principal Investigator, Monitor and Sponsor"



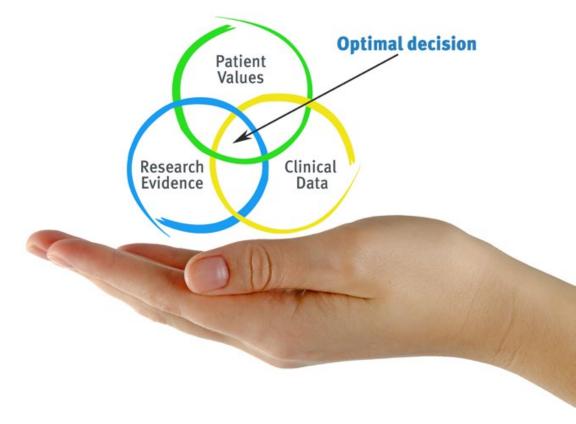


tech 26 | Methodology

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.





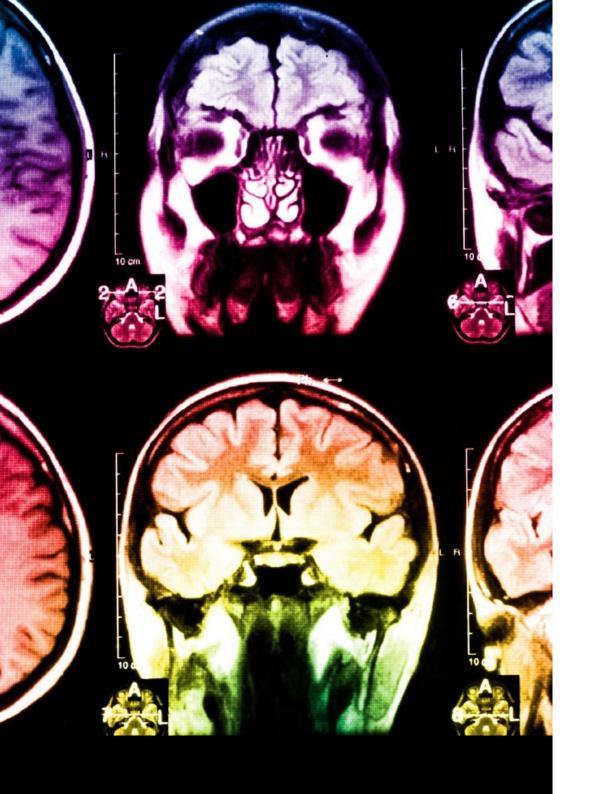
Relearning Methodology

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.





Methodology | 29 tech

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

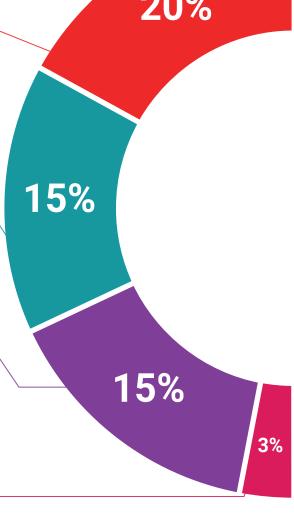
TECH introduces students to the latest techniques, the latest educational advances and to the forefront of current and procedures of veterinary techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch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



Testing & Retesting

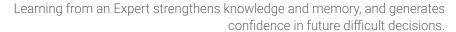
We periodically evaluate and re-evaluate students' knowledge throughout the program, through assessment and self-assessment activities and exercises, so that they can see how they are achieving their goals.

and direct way to achieve the highest degree of understanding.



Classes

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

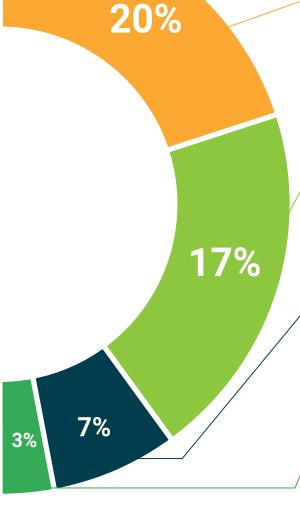




Quick Action Guides

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.









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This Postgraduate Certificate in Clinical Trials, Principal Investigator, Monitor and Sponsor contains the most complete and up-to-date scientific program on the market.

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

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

Title: Postgraduate Certificate in Clinical Trials, Principal Investigator, Monitor and Sponsor

Official No of Hours: 300 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.

technological university

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