



Postgraduate Certificate

Clinical Trial Monitoring for Nursing

» Modality: online

» Duration: 12 weeks

» Certificate: TECH Technological University

» Dedication: 16h/week

» Schedule: at your own pace

» Exams: online

Website: www.techtitute.com/in/nursing/postgraduate-certificate/clinical-trials-monitoring-nursing

Index

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06 Certificate

p. 32





tech 06 | Introduction

The Postgraduate Certificate in Clinical Trial Monitoring for Nursing offers professionals in this field a global vision of the monitoring process, so that the nurse can learn specialized knowledge that will serve as a guide for the performance of this work in a specialized center.

Specifically, this program will analyze the design of the protocol, from which the entire clinical trial is developed, and will assess the responsibility of the sponsor to verify the adequate and effective monitoring of the clinical trial.

Another of the strengths of this program is the development of Monitoring, establishing the most common protocol deviations and specifying solutions for specific cases.

Relevant aspects such as the monitoring visit and the closing visit, essential documents and source documents, or how to work, in daily practice, with the use of data collection notebooks, among other aspects, will, analyzed.

In short, a global vision of the monitoring process is presented, so that the healthcare professional will be able to acquire specialized knowledge that will serve as a guide for carrying out this work in a specialized center.

This **Postgraduate Certificate in Clinical Trial Monitoring for Nursing** 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 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
- New developments in Clinical Trials
- Practical exercises where the self-assessment process can be carried out to improve learning
- Special emphasis on innovative methodologies in Clinical Trials
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection work
- Content that is accessible from any fixed or portable device with an internet connection



Expand your knowledge through this Postgraduate Certificate that will allow you to specialize until you achieve excellence in this field"



This Postgraduate Certificate is the best investment you can make when selecting a refresher program, for two reasons: in addition to updating your knowledge in Clinical Trials Monitoring, you will obtain a qualification endorsed by TECH"

The teaching staff includes professionals from the Health field, who bring their 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.

The design of this program focuses on problem-based learning, by means of which the healthcare professional must try to solve the different professional practice situations that arise throughout the academic program. For this purpose, the professional will be assisted by an innovative interactive video system developed by renowned and experienced experts in the field of Clinical Trials

Do not hesitate to take this educational program with us. You will find the best teaching material with virtual lessons.

This 100% online Postgraduate Certificate will allow you to balance your studies with your professional work while increasing your knowledge in this field.







tech 10 | Objectives



General objectives

- Establish the different roles that exist in the figure of the clinical trial sponsor, their function and their relationship with the research center
- Substantiate the concept of Monitoring
- Analyze the content of a clinical research protocol and recognize the commitment that a good compliance with it entails
- Master the skills necessary for project development and management
- Define the process of monitoring a clinical trial, with the necessary documentation, tools and guidance for this role, taking into account the main problems that may be encountered
- Present the latest scientific advances in clinical trial monitoring tasks, with knowledge adapted to the real needs of companies in the pharmaceutical sector
- Present the wide range of tasks involved in conducting a CE and what is involved at each stage of the clinical trial
- Explain the practical aspects of conducting a CE and the role of the clinical trial monitor



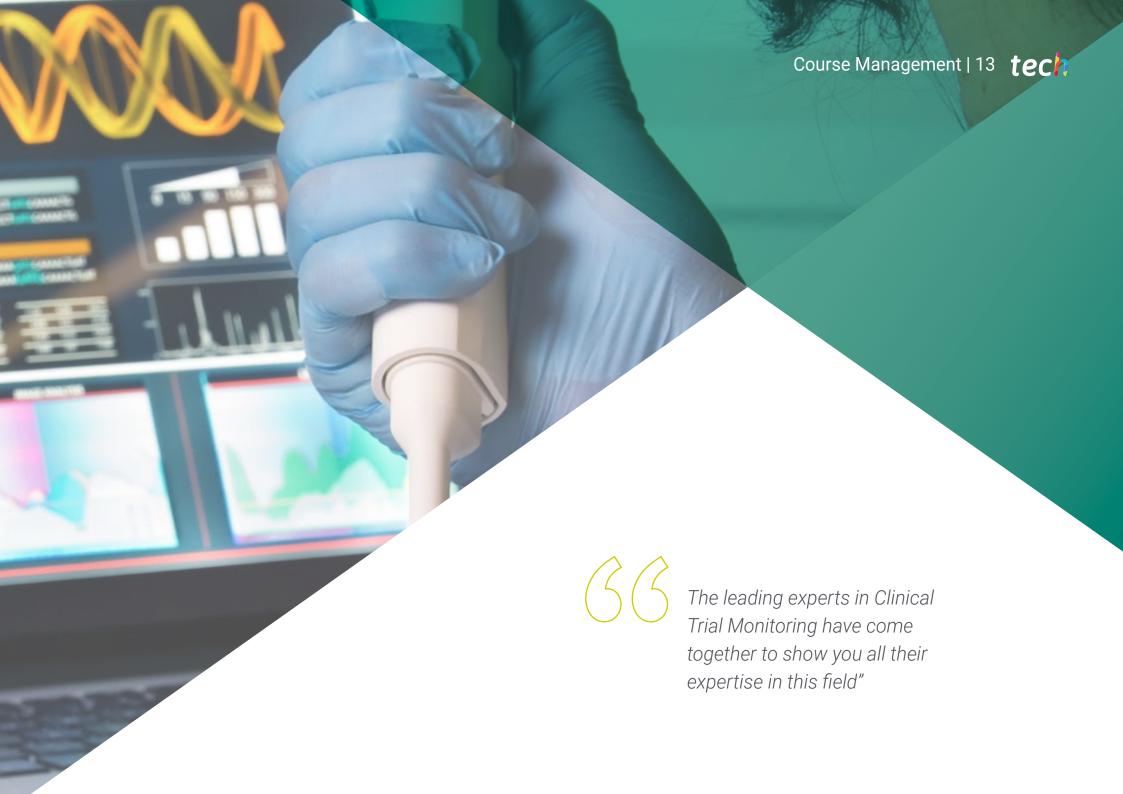


Specific objectives

- Specify both the professional profile of the clinical trial monitor and the skills that must be developed to carry out the monitoring process of a clinical trial
- Establish your responsibility in the selection of the center and in the initiation of the study
- Justify the importance of the monitor in ensuring the correct compliance with the procedures and activities established by the protocol and the standards of good clinical practice during the trial
- Generate knowledge on the practical aspects of visits prior to the start of the clinical trial
- Present the basis for the essential documentation for the implementation of the clinical trial at the center
- Prepare the student in the correct handling of a pre-selection visit and initiation in the research center
- Assess the involvement of the Hospital Pharmacy Service in the management, control and traceability of the medication in the study
- Justify the importance of maintaining good communication between team members involved in the development of a clinical trial
- Establish the basic points of a monitoring and closing visit

- Develop the monitor's Monitoring plan and Standard Operating Procedures (SOPs) at each stage of the clinical trial
- Present a data collection notebook and specify how to keep it up to date
- Establish the data collection process to assess safety in a clinical trial. Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Reproduce the management of a monitoring visit
- Analyze the most common protocol deviations
- Establish the important documents for a clinical trial
- Submit a clinical trial monitor's guideline (Monitoring Plan)
- Present the data collection notebooks
- Develop important theoretical knowledge about closeout visits
- Establish the documentation to be prepared for closeout visits
- Specify the points to be reviewed in the closeout visits





tech 14 | Course Management

Management



Dr. Gallego Lago, Vicente

- Military pharmacist at HMC Gómez Ulla
- Doctoral studies with the qualification of Outstanding
- Honors Degree in Pharmacy from the Complutense University of Madrid
- Resident Internal Pharmacist Examination (F.I.R) obtaining the No. 1 in this selective test
- Resident Internal Pharmacist (F.I.R) of the Pharmacy Service of the "12 de Octubre Hospital

Professors

Ms. Benito Zafra, Ana

- Graduate in Biology from the Autonomous University of Madrid
- Master's Degree in Biochemistry, Molecular Biology and Biomedicine from the Complutense University of Madrid
- Coordinator of clinical trials and projects in the Heart Failure Unit at the Cardiology Department of the 12 de Octubre Hospital of Madrid

Ms. De Torres Pérez, Diana

- $\bullet\,$ Degree in Pharmacy from the Complutense University of Madrid
- Master's Degree in Coordination of Clinical Trials at ESAME
- Master's Degree in Study Coordinator in ESAME Pharmaceutical- Business School
- Trial Coordinator at the 12 de Octubre University Hospital, Cardiology Service (Hemodynamics and Arrhythmias)



Course Management | 15 tech

Dr. Cano Armenteros, Montserrat

- Teacher of Compulsory Secondary Education (ESO) of Biology and Geology at the Azorín public high school
- Master's Degree in Clinical Trials University of Seville
- Official Master's Degree in Primary Care Research from the University of Chicago
- Certificate of Pedagogical Aptitude (CAP) University of Alicante
- Bachelor's Degree in Biology. University of Alicante

Ms. Onteniente Gomis, María del Mar

- Degree in Veterinary Medicine from the University of Córdoba
- 10 years of experience in consultation and anesthesia in companion animals



A path to achieve education and professional growth that will propel you towards a greater level of competitiveness in the employment market"





tech 18 | Structure and Content

Module 1. Monitoring of Clinical Trials I

- 1.1. Promoter I
 - 1.1.1. General Aspects
 - 1.1.2. Promoter Responsibilities
- 1.2. Promoter II
 - 1.2.1. Project Management
 - 1.2.2. Non-commercial Research
- 1.3. Protocol
 - 1.3.1. Definition and Content
 - 1.3.2. Protocol Compliance
- 1.4. Monitoring
 - 1.4.1. Introduction
 - 1.4.2. Definition
 - 1.4.3. Monitoring Objectives
 - 1.4.4. Types of Monitoring: Traditional and Risk-Based
- 1.5. Clinical Trial Monitor I
 - 1.5.1. Who can be a Monitor?
 - 1.5.2. CRO: Clinical Research Organization
 - 1.5.3. Monitoring Plan
- 1.6. The Monitor II
 - 1.6.1. Monitors Responsibilities
 - 1.6.2. Verification of Source Documents Source Documents Verification (SDV)
 - 1.6.3. Monitors Report and Monitoring Letter
- 1.7. Selection Visit
 - 1.7.1. Researcher Selection
 - 1.7.2. Aspects to Take into Account
 - 1.7.3. Suitability of Facilities
 - 1.7.4. Visit to other Hospital Services
 - 1.7.5. Deficiencies in Study Facilities and Staffing
- 1.8. STARTUP in a Clinical Research Center
 - 1.8.1. Definition and Functionality
 - 1.8.2. Essential Documents at the Beginning of the Trial





Structure and Content | 19 tech

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- 1.9.1. Objective
- 1.9.2. Preparing the Initiation Visit
- 1.9.3. Investigators File
- 1.9.4. Investigator Meeting
- 1.10. Initial Visit in Hospital Pharmacy
 - 1.10.1. Objective
 - 1.10.2. Investigational Drug Management
 - 1.10.3. Controlling Temperature
 - 1.10.4. General Deviation Procedure

Module 2. Monitoring of Clinical Trials II

2.1. Follow-Up Visit

- 2.1.1. Preparation
 - 2.1.1.1. Letter Confirming the Visit
 - 2.1.1.2. Preparation
- 2.1.2. Center Development
 - 2.1.2.1. Documentation Review
 - 2.1.2.2. SAEs
 - 2.1.2.3. Inclusion and Exclusion Criteria
 - 2.1.2.4. Collate
- 2.1.3. Research Team Training
 - 2.1.3.1. Monitoring
 - 2.1.3.1.1. Monitoring Report
 - 2.1.3.1.2. Issues Tracking
 - 2.1.3.1.3. Team Support
 - 2.1.3.1.4. Monitoring Letter

tech 20 | Structure and Content

2.1.3.2. Temperature		Close-Out Visit		
2.1.3.2.1. Adequate Medication		2.2.1.	Definition	
2.1.3.2.2. Reception		2.2.2.	Reasons for Close-Out Visits	
2.1.3.2.3. Expiration			2.2.2.1. Completion of the Clinical Trial	
2.1.3.2.4. Dispensing			2.2.2.2. Not Complying with Protocol	
2.1.3.2.5. Setting Up			2.2.2.3. Not Complying with Good Clinical Practices	
2.1.3.2.6. Return			2.2.2.4. At the Investigators Request	
2.1.3.2.7. Storage			2.2.2.5. Low Recruitment	
2.1.3.2.8. Documentation		2.2.3.	Procedures and Responsibilities	
2.1.3.3. Samples			2.2.3.1. Before the Close-Out Visit	
2.1.3.3.1. Local and Central			2.2.3.2. During the Close-Out Visit	
2.1.3.3.2. Types			2.2.3.3. After the Close-Out Visit	
2.1.3.3.3. Temperature Registration		2.2.4.	Pharmacy Close-Out Visit	
2.1.3.3.4. Calibration/Maintenance Certificate		2.2.5.	Final Report	
2.1.3.4. Meeting with the Research Team		2.2.6.	Conclusions	
2.1.3.4.1. Signature of Pending Documentation	2.3.	Queries	s Management, Database Slicing	
2.1.3.4.2. Discussion of Findings		2.3.1.	Definition	
2.1.3.4.3. Re-Training		2.3.2.	Queries Rules	
2.1.3.4.4. Corrective Actions		2.3.3.	How are Queries Generated?	
2.1.3.5. Review of ISF (Investigator Site File)			2.3.3.1. Automatically	
2.1.3.5.1. Clinical Investigations (CIs) and Protocols			2.3.3.2. By the Monitor	
2.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS			2.3.3.3. By an External Reviewer	
2.1.3.5.3. LOGs		2.3.4.	When are Queries Generated?	
2.1.3.5.4. Site Visit Letter			2.3.4.1. After a Monitoring Visit	
2.1.3.5.5. New Documentation			2.3.4.2. Close to Closing a Database	
2.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)		2.3.5.	Query Status	
2.1.3.6.1. Concept			2.3.5.1. Open	
2.1.3.6.2. Principal Investigator Review			2.3.5.2. Pending Revision	
2.1.3.7. Electronic Notebook			2.3.5.3. Closed	
		2.3.6.	Database Slicing	
			2.3.6.1. Most Frequent Database Slicing Errors	
		2.3.7.	Conclusions	

- 2.4. AE Management and SAE Notification
 - 2.4.1. Definitions
 - 2.4.1.1. Adverse Events Adverse Event (AE)
 - 2.4.1.2. Adverse Reactions (AR)
 - 2.4.1.3. "Serious Adverse Event" (SAE) or Serious Adverse Reaction (SAR)
 - 2.4.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR) (SUSAR)
 - 2.4.2. Data to be Collected by the Researcher
 - 2.4.3. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
 - 2.4.3.1. Description
 - 2.4.3.2. Dates
 - 2.4.3.3. Unraveling
 - 2.4.3.4. Intensity
 - 2.4.3.5. Actions Taken
 - 2.4.3.6. Causality Relationship
 - 2.4.3.7. Basic Questions
 - 2.4.3.7.1. Who Notifies, What is Notified, Who is Notified, How are they Notified, When are they Notified?
 - 2.4.4. Procedures for the Communication of AE/AR with Investigational Drugs
 - 2.4.4.1. Expedited Notification of Individual Cases
 - 2.4.4.2. Periodic Security Reports
 - 2.4.4.3. "Ad Hoc" Security Reports
 - 2.4.4.4. Annual Reports
 - 2.4.5. Special Interest Events
 - 2.4.6. Conclusions

- 2.5. Clinical Research Associate (CRA) Standard Operating Procedures Standard Operating Procedures (SOP)
 - 2.5.1. Definition and objectives
 - 2.5.2. Writing a SOP
 - 2.5.2.1. Procedure
 - 2.5.2.2. Format
 - 2.5.2.3. Implementation
 - 2.5.2.4. Review
 - 2.5.3. SOP Feasibility and Site Qualification Visit
 - 2.5.3.1 Procedures
 - 2.5.4 SOP Initiation Visit
 - 2.5.4.1. Procedures Prior to the Initiation Visit
 - 2.5.4.2. Procedures During the Initiation Visit
 - 2.5.4.3. Monitoring Initiation Visit Procedures
 - 2.5.5. SOP Monitoring Visit
 - 2.5.5.1. Procedures Prior to the Monitoring Visit
 - 2.5.5.2. Procedures During the Monitoring Visit
 - 2.5.5.3. Monitoring Letter
 - 2.5.6. SOP for Close-Out Visit
 - 2.5.6.1. Preparing the Close-Out Visit
 - 2.5.6.2. Manage the Close-Out Visit
 - 2.5.6.3. Monitoring After a Close-Up Visit
 - 2.5.7. Conclusions
- 2.6. Quality Assurance: Audits and Inspections
 - 2.6.1. Definition
 - 2.6.3. Types of Audits
 - 2.6.3.1. Internal Audits
 - 2.6.3.2. External Audits or Inspections
 - 2.6.4. How Prepare an Audit
 - 2.6.5. Principal Findings
 - 2.6.6. Conclusions

tech 22 | Structure and Content

2.7. Protocol Deviations 2.7.1. Criteria 2.7.1.1. Non-Compliance with Inclusion Criteria 2.7.1.2. Compliance with Exclusion Criteria 2.7.2. International Classification of Functioning (ICF) Deficiencies 2.7.2.1. Correct Signatures on Documents (CI, LOG) 2.7.2.2. Correct Dates 2.7.2.3. Correct Documentation 2.7.2.4. Correct Storage 2.7.2.5. Correct Version Out-Of-Window Visits 2.7.4. Poor or Wrong Documentation 2.7.5. The 5 Rights Medication Administration 2.7.5.1. Right Patient 2.7.5.2. Right Drug 2.7.5.3. Right Time 2.7.5.4. Right Dose 2.7.5.5. Right Route 2.7.6. Missing Samples and Parameters 2.7.6.1. Missing Samples 2.7.6.2. Parameter Not Performed 2.7.6.3. Sample Not Sent on Time 2.7.6.4. Time of Sample Collection 2.7.6.5. Request for Kits Out of Time 2.7.7. Information Privacy 2.7.7.1. Information Security 2.7.7.2. Reporting Security 2.7.7.3. Photo Security 2.7.8. Temperature Deviations 2.7.8.1. Register 2.7.8.2. Inform

2.7.8.3. Act



- 2.7.9. Open Blinding at the Wrong Time
- 2.7.10. PI Availability
 - 2.7.10.1. Not Updated in Interactive Voice Response Services (IVRS)
 - 2.7.10.2. Not Sent on Time
 - 2.7.10.3. Not Registered on Time
 - 2.7.10.4. Broken Stock
- 2.7.11. Forbidden Medication
- 2.7.12. Key and Non-Key
- 2.8. Source and Essential Documents
 - 2.8.1. Features
 - 2.8.2. Source Documents Location
 - 2.8.3. Source Document Access
 - 2.8.4. Source Document Types
 - 2.8.5. How to Correct a Source Document
 - 2.8.6. Source Document Retention Time
 - 2.8.7. Main Components of the Medical History
 - 2.8.8. Investigator's Brochure (IB)
- 2.9. Monitoring Plan
 - 2.9.1. Visits
 - 2.9.2. Frequency (F)
 - 2.9.3. Organisation
 - 2.9.4. Confirmation
 - 2.9.5. Site Issues Categorization
 - 2.9.6. Communication with Researchers
 - 2.9.7. Research Team Training
 - 2.9.8. Trial Master File
 - 2.9.9. Reference Documents
 - 2.9.10. Electronic Notebooks Remote Review
 - 2.9.11. Data Privacy
 - 2.9.12. Center Management Activities

- 2.10. Data Collection Notebooks
 - 2.10.1. Concept and History
 - 2.10.2. Timeline Compliance
 - 2.10.3. Data Validation
 - 2.10.4. Management of Data Inconsistencies or Queries
 - 2.10.5. Data Exports
 - 2.10.6. Security and Roles
 - 2.10.7. Traceability and Logs
 - 2.10.8. Report Generation
 - 2.10.9. Notifications and Alerts
 - 2.10.10. Electronic Notebook vs. Paper Notebook





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.

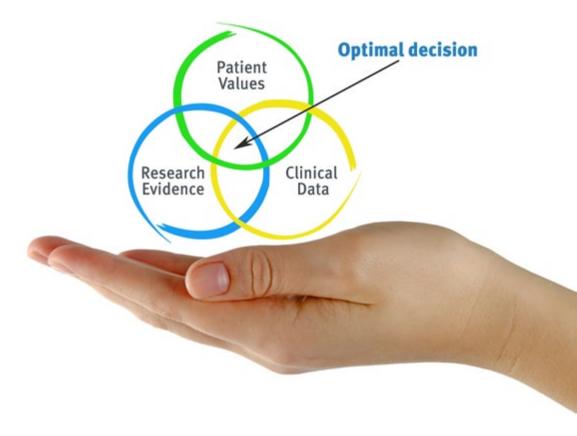


tech 26 | Methodology

At TECH Nursing School we use the Case Method

In a given situation, what should a professional do? Throughout the program, students will face multiple simulated clinical cases, based on real patients, in which they will have to do research, establish hypotheses, and ultimately resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Nurses learn better, faster, and more sustainably over time.

With TECH, nurses can experience a learning methodology 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 real conditions in professional nursing 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:

- Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
- 2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into the hospital setting or primary care.
- 3. Ideas and concepts are understood more efficiently, given that the example situations are based on real-life.
- 4. Students like to feel that the effort they put into their studies is worthwhile. This then translates into a greater interest in learning and more 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 case studies with a 100% online learning system based on repetition combining a minimum of 8 different elements in each lesson, which is a real revolution compared to the simple study and analysis of cases.

The nurse will learn through real cases and by solving 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 we have trained more than 175,000 nurses with unprecedented success in all specialities regardless of practical workload. Our pedagogical methodology is developed in a highly competitive environment, with a university student body with a strong socioeconomic profile and an average age of 43.5 years old.

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

In our program, learning is not a linear process, but rather a spiral (learn, unlearn, forget, and relearn). 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 really specific and precise.

These contents are then adapted in 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.



Nursing Techniques and Procedures on Video

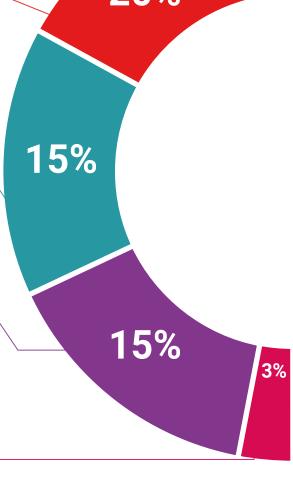
We introduce you to the latest techniques, to the latest educational advances, to the forefront of current medical techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch them as many times as you want.



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

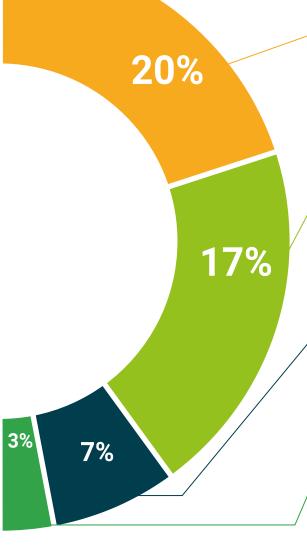
There is scientific evidence suggesting that observing third-party experts can be useful.

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.







tech 34 | Certificate

This **Postgraduate Certificate in Clinical Trial Monitoring for Nursing** ccontains 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 certificate 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 Trial Monitoring for Nursing Official N° of hours: **300 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.

technological university



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