Postgraduate Certificate

Clinical Trials Coordination for Nursing

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Postgraduate Certificate

Clinical Trials Coordination for Nursing

- Modality: **online**
- Duration: **12 weeks**
- Certificate: **TECH Global University**
- Accreditation: **12 ECTS**
- Schedule: **at your own pace**
- Exams: **online**

Website: **www.techtitute.com/us/nursing/postgraduate-certificate/coordination-clinical-trials-nursing**

Index

01

Introduction

Controlling all the processes of a clinical trial is a fundamental task of the coordinator, since, if any process fails, the study could be lost. For this reason, TECH has committed itself to qualify nurses in this very important field with the most complete education on the market.

The Coordination of Clinical Trials is essential to maintain control of the research and to verify that no errors occur during the process. Study with us and expand your knowledge in this field"

In recent years, the figure of Clinical Trials Coordinator has become a fundamental and essential part of a research unit. There is an increasing demand from developers for a person to organize the research team and to serve as a link between the pharmaceutical industry and the research center itself.

This Postgraduate Certificate in Clinical Trials Coordination is designed for students to acquire the necessary skills and abilities so that there can be no errors in this part of the process. And, for this, TECH wants to offer you this very complete program developed by a team specialized in everything related to Clinical Trials.

In addition, emphasis is placed on the investigator's file, where all the documentation related to the research team (curriculum vitae and other relevant documents evidencing the qualification of the investigators) and the patient (informed consents, recruitment measures, monitoring visits), the study protocol, the investigator's manual, a model of the data collection notebook, and the different laboratory and safety procedures are recorded, so their custody must be carried out in an appropriate manner.

This program is delivered completely online, so it will be the students themselves who decide from where to study and at what time to do it, so that the completion of this Postgraduate Certificate will not prevent them from continuing with the rest of their daily obligations, both professional and personal.

This **Postgraduate Certificate** in **Clinical Trials Coordination 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 Coordination
- 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 Coordination of Trials
- Practical exercises where the self-assessment process can be carried out to improve learning
- Special emphasis on innovative methodologies in Clinical Coordination of 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 Trial Coordination, you will obtain a certificate from TECH"

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 expanding your knowledge in this field.

The teaching staff includes professionals from the Health sector, 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.

02

Objectives

The Postgraduate Certificate in Clinical Trial Coordination for Nursing is aimed at facilitating the performance of the research professional with the latest advances in the field.

Thanks to this Postgraduate Certificate you will be able to specialize in Clinical Trials Coordination and learn about the latest advances in the subject"

General Objectives

- Prepare the student in the handling and management of researcher's archive documentation in accordance with current regulations, the GCP and ICH guidelines
- Develop legislative knowledge governing the documentation of the investigator's file
- Analyze the importance of the role of the trial coordinator in clinical research
- Specify the main functions of the research team and their involvement with the patient
- Establish the main components of a clinical trial and observational study

Make the most of this opportunity and take the step to get up to date on the latest developments in Clinical Trials Coordination for Nursing"

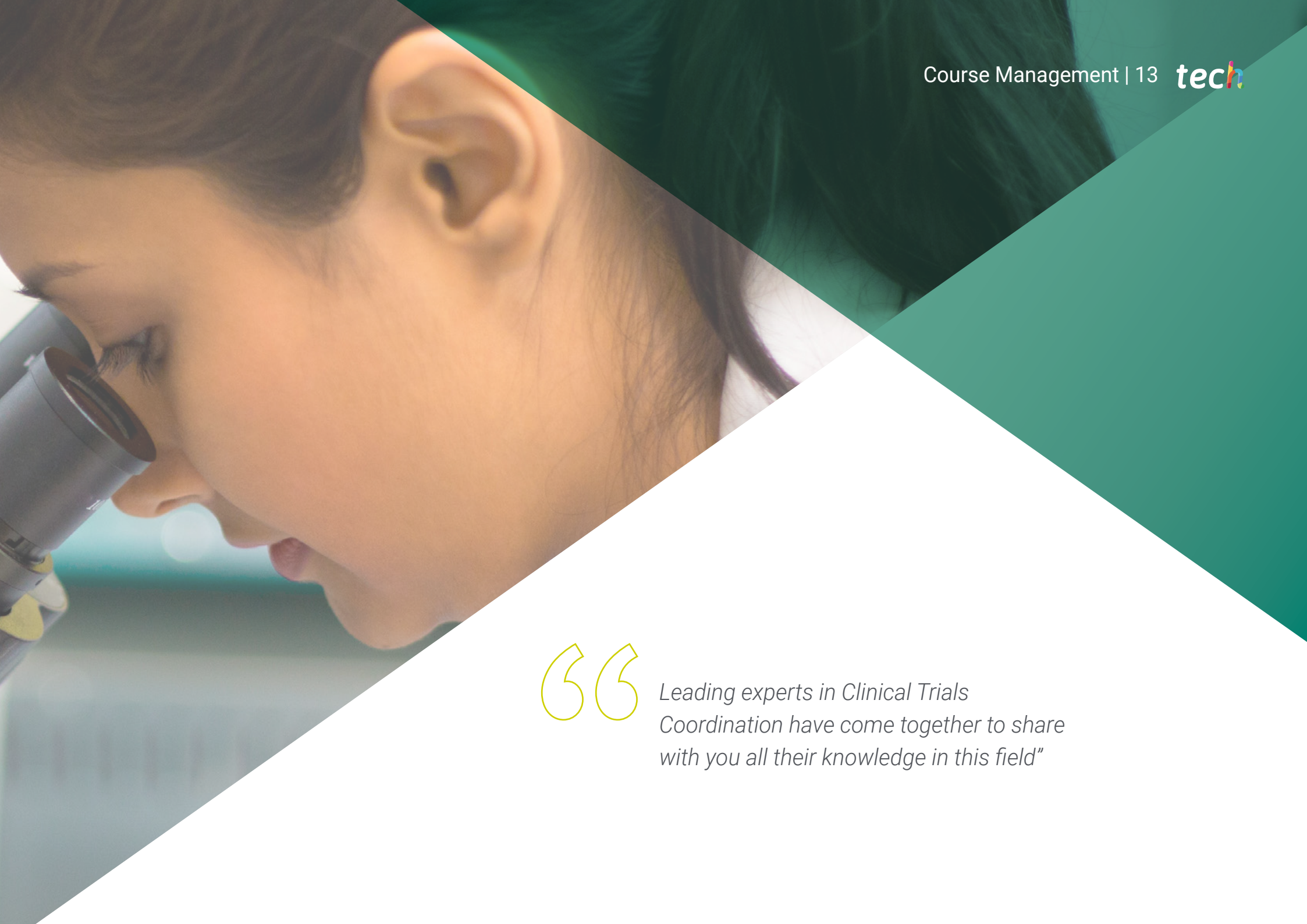
Specific Objectives

- Specify the mandatory documents and forms that must be included in the researcher's file
- Establish how to best manage the archive at the beginning, during and at the end of the study: storing, updating and ordering documentation
- Define the steps to be followed to complete the documents and forms for the researchers file
- Substantiate the necessary skills to be developed in order to perform the work of the trial coordinator
- Define the organization and preparation of both the research team and the center for their inclusion in a clinical trial, managing the CV, good clinical practices, suitability of the facilities, etc
- Reproduce the tasks to be performed in both a clinical trial and an observational study
- Analyze a clinical trial protocol through theoretical and practical examples.
- Determine the work of a coordinator in their work center under a clinical trial protocol (patients, visits, tests)
- Develop the skills necessary for the use of a data collection notebook: data entry, query resolution and sample processing
- Compile the different types of pharmacological treatments that can be used in a clinical trial (placebo, biological) and their management

03

Course Management

The program's teaching staff includes leading experts in research and health, who contribute their work experience to this education. In addition, other renowned experts participate in its design and development, completing the program in an interdisciplinary manner.



Leading experts in Clinical Trials Coordination have come together to share with you all their knowledge in this field"

Management

Dr. Gallego Lago, Vicente

- Military pharmacist at HMC Gómez Ulla
- Doctoral studies with the qualification of Outstanding
- Degree in Pharmacy, Complutense University of Madrid with a diploma for obtaining an Honorary Degree
- 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. Gómez Abecia, Sara

- Clinical Research Project Manager
- Biology Graduate
- Master in Clinical Trials

Dr. Dompablo Tobar, Mónica

- Researcher at the Psychiatry Department of the Hospital Universitario 12 de Octubre
- Degree in Psychology from the Autonomous University of Madrid
- PhD in Psychology from the Complutense University of Madrid. Oustanding Cum Laude

D. Bravo Ortega, Carlos

- Coordinator of clinical trials in the Clinical Nephrology Service of the 12 de Octubre Hospital
- Degree in Biology from the University of Alcalá de Henares
- Master's Degree in Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

Ms. Jiménez Fernández, Paloma

- Coordinator of clinical trials in the Rheumatology Service of the 12 de Octubre Hospital
- Graduate in Pharmacy from the Complutense University of Madrid.
- Master's Degree in Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

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

04

Structure and Content

The structure of the contents has been designed by the best professionals in research and health, with an extensive background and recognized prestige in the profession, backed by the volume of cases reviewed, studied and diagnosed, and with extensive mastery of new technologies.

This course contains the most complete and up-to-date program on the market"

Module 1. Coordination of Clinical Trials I

1.1. The Researcher's File – General Aspects
- 1.1.1. What is the Researcher's File? What type of Documentation Should It Contain and Why? How Long Should the Information be Stored?
- 1.1.2. Contract
  - 1.1.2.1. Original Copies
  - 1.1.2.2. Amendments
- 1.1.3. Ethical Committees
  - 1.1.3.1. Approvals
  - 1.1.3.2. Amendments
- 1.1.4. Regulatory Authorities
  - 1.1.4.1. Approvals
  - 1.1.4.2. Modifications
  - 1.1.4.3. Monitoring and Final Reports
- 1.1.5. Civil Liability Insurance

1.2. Documentation Associated with the Research Team
- 1.2.1. CV
- 1.2.2. Good Clinical Practice Certificate
- 1.2.3. Specific Education Certificates
- 1.2.4. Signed Statement of the Investigator, Financial Disclosure
- 1.2.4. Task Delegation

1.3. Study Protocol and Monitoring
- 1.3.1. Protocol Versions, Summary and Pocket Guides
- 1.3.2. Protocol
- 1.3.3. Protocol Amendments
- 1.3.4. Protocol Signature Form

1.4. Patient Related Material
- 1.4.1. Patient Information Form and Informed Consent Form (Copies and Specimens for Signature)
- 1.4.2. Modifications to the Consent (Copies and Specimens for Signature)
- 1.4.3. Study Participation Cards
- 1.4.4. Information for Primary Care Physician
- 1.4.5. Questionnaires

1.5. Patient Forms, Monitoring Visits
- 1.5.1. Patient (Screening) Form
- 1.5.2. Patient Recruitment and Identification Form
- 1.5.3. Visit Logs and Reports Form

1.6. Data Collection Notebooks (DCNs)
- 1.6.1. Types
- 1.6.2. Guide or Manual for Data Entry in the DCN
- 1.6.3. Copy of DCN

1.7. Investigator's Brochure (Studies with Medical Devices) or Fact Sheet (Clinical Trials with Medication)
- 1.7.1. Researcher's Manual
- 1.7.2. Technical Data Sheets of the Drugs Under Study (If Marketed)
- 1.7.3. Instructions for the Control of Specific Parameters (example)
- 1.7.4. Instructions for Return of Medication or Medical Devices

1.8. Material Related to Laboratory and Specific Procedures
- 1.8.1. Central Laboratories and Sample Shipping Documents
- 1.8.2. Local Laboratory: Qualification Certificates and Ranks
- 1.8.3. Instructions for Acquiring and/or Processing Medical Images
- 1.8.4. Sample and Material Shipment

1.9. Security
- 1.9.1. Adverse Events and Serious Adverse Events
- 1.9.2. Notification Instructions
- 1.9.3. Relevant Security Correspondence

1.10. Others
- 1.10.1. Contact Information
- 1.10.2. Note to File
- 1.10.3. Correspondence with the Promoter
- 1.10.4. Acknowledgements of Receipt
- 1.10.5. Newsletter

Module 2. Coordination of Clinical Trials II

2.1. Research Team
- 2.1.1. Components of a Research Team
  - 2.1.1.1. Principal Investigator
  - 2.1.1.2. Sub-Investigator
  - 2.1.1.3. Coordinator
  - 2.1.1.4. Rest of the Team
- 2.1.2. Responsibilities of the Research Team
  - 2.1.2.1. Compliance with Good Clinical Practices and Current Legislation
  - 2.1.2.2. Compliance of the Study Protocol
  - 2.1.2.3. Care and Maintenance of the Research Archive
- 2.1.3. Task Delegation
  - 2.1.3.1. Document Details
  - 2.1.3.2. Example

2.2. Trial Coordinator
- 2.2.1. Responsibilities
  - 2.2.1.1. Primary Responsibilities
  - 2.2.1.2. Secondary Responsibilities
- 2.2.2. Capabilities and Competencies
  - 2.2.2.1. Academic Background
  - 2.2.2.2. Skills
- 2.2.3. Clinical Trials vs. Observational Study
  - 2.2.3.1. Types of Clinical Trials
  - 2.2.3.2. Types of Observational Studies

2.3. Documentation Required to Initiate Clinical Trial
- 2.3.1. Curriculum of the Research Team
  - 2.3.1.1. Basic Notions of a Research Curriculum
  - 2.3.1.2. Good Clinical Practice Example
- 2.3.2. Good Clinical Practice
  - 2.3.2.1. Origin of Good Clinical Practices
  - 2.3.2.2. How to Get Certified?
  - 2.3.2.3. Expiration
- 2.3.3. Suitability of the Research Team
  - 2.3.3.1. Who Signs the Document?
  - 2.3.3.2. Presentation to Ethics Committee
- 2.3.4. Suitability of Facilities
  - 2.3.4.1. Who Signs the Document?
  - 2.3.4.2. Ethical Committee Presentation
- 2.3.5. Calibration Certificates
  - 2.3.5.1. Calibration
  - 2.3.5.2. Calibration Equipment
  - 2.3.5.3. Valid Certifications
  - 2.3.5.4. Expiration
- 2.3.6. Other Training
  - 2.3.6.1. Necessary Certifications According Protocol

2.4. Main Functions Trial Coordinator
- 2.4.1. Documentation Preparation
  - 2.4.1.1. Documentation Requested for Approval of the Study at the Center
- 2.4.2. Investigator Meeting
  - 2.4.2.1. Importance
  - 2.4.2.2. Attendees
- 2.4.3. Initiation Visit
  - 2.4.3.1. Duties of the Coordinator
  - 2.4.3.2. Functions of the Principal Investigator and Subinvestigators
  - 2.4.3.3. Monitor
- 2.4.4. Monitoring Visit
  - 2.4.4.1. Preparation After a Monitoring Visit
  - 2.4.4.2. Functions During the Monitoring Visit
- 2.4.5. End-Of-Study Visit
  - 2.4.5.1. Storage of the Researchers File

2.5. Relationship with the Patient
- 2.5.1. Preparation of Visits
  - 2.5.1.1. Consents and Amendments
  - 2.5.1.2. Visit Window
  - 2.5.1.3. Identify the Responsibilities of the Investigation Team during the Visit
  - 2.5.1.4. Visit Calculator
  - 2.5.1.5. Preparation of Documentation to be Used During the Visit
- 2.5.2. Complementary Tests
  - 2.5.2.1. Analysis
  - 2.5.2.2. Chest X-Ray
  - 2.5.2.3. Electrocardiogram
- 2.5.3. Calendar of Visits
  - 2.5.3.1. Example

2.6. Samples
- 2.6.1. Equipment and Materials Necessary
  - 2.6.1.1. Centrifuge
  - 2.6.1.2. Incubator
  - 2.6.1.3. Refrigerators
- 2.6.2. Processing of Samples
  - 2.6.2.1. General Procedure
  - 2.6.2.2. Example
- 2.6.3. Laboratory Kits
  - 2.6.3.1. What Are They?
  - 2.6.3.2. Expiration
- 2.6.4. Shipment of Samples
  - 2.6.4.1. Sample Storage
  - 2.6.4.2. Ambient Temperature Shipment
  - 2.6.4.3. Shipping Frozen Samples

2.7. Data Collection Notebooks
- 2.7.1. What Is It?
  - 2.7.1.1. Types of Notebooks
  - 2.7.1.2. Paper Notebook
  - 2.7.1.3. Electronic Notebook
  - 2.7.1.4. Specific Notebooks According to Protocol
- 2.7.2. How To Complete It?
  - 2.7.2.1. Example
- 2.7.3. Query
  - 2.7.3.1. What Is a Query?
  - 2.7.3.2. Resolution Time
  - 2.7.3.3. Who Can Open a Query?

2.8. Randomization Systems
- 2.8.1. What Is It?
- 2.8.2. Types of IWRS:
  - 2.8.2.1. Telephonics
  - 2.8.2.2. Electronics
- 2.8.3. Responsibilities Researcher Vs. Research Team
  - 2.8.3.1. Screening
  - 2.8.3.2. Randomization
  - 2.8.3.3. Scheduled Visits
  - 2.8.3.4. Unscheduled Visits
  - 2.8.3.5. Blinding Opening
- 2.8.4. Medication
  - 2.8.4.1. Who Receives the Medication?
  - 2.8.4.2. Drug Traceability
- 2.8.5. Return of Medication
  - 2.8.5.1. Functions of the Research Team in the Return of Medication

2.9. Biological Treatments
- 2.9.1. Coordination of Clinical Trials with Biologics
  - 2.9.1.1. Biological Treatments
  - 2.9.1.2. Types of Treatment
- 2.9.2. Types of Studies
  - 2.9.2.1. Biological Criteria Placebo
  - 2.9.2.2. Biological Criteria Biological
- 2.9.3. Biological Management
  - 2.9.3.1. Administration.
  - 2.9.3.2. Traceability
- 2.9.4. Rheumatic Diseases
  - 2.9.4.1. Rheumatoid Arthritis
  - 2.9.4.2. Psoriatic Arthritis
  - 2.9.4.3. Lupus
  - 2.9.4.4. Scleroderma

This will be a key specialization to advance your career"

05

Methodology

This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning.**

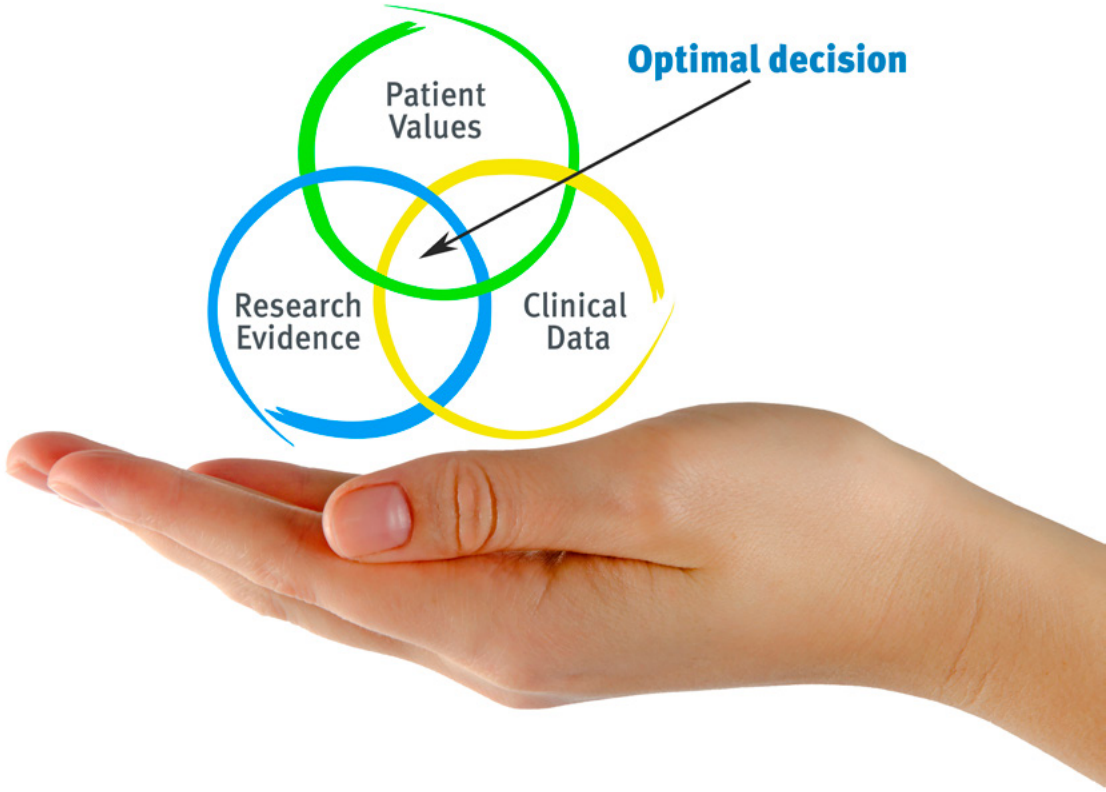
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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 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:

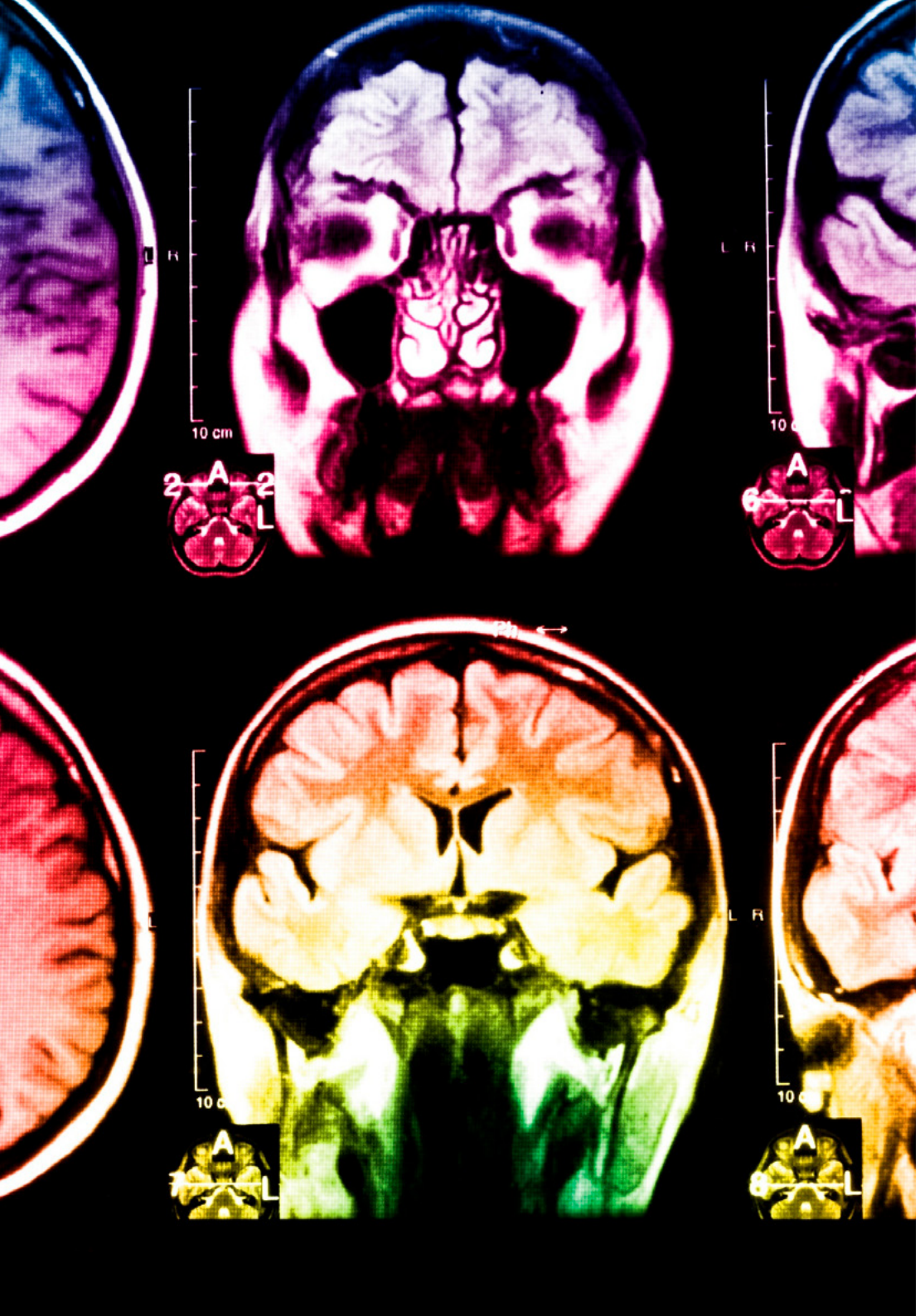
1. Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into 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.



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 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 really 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.

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.

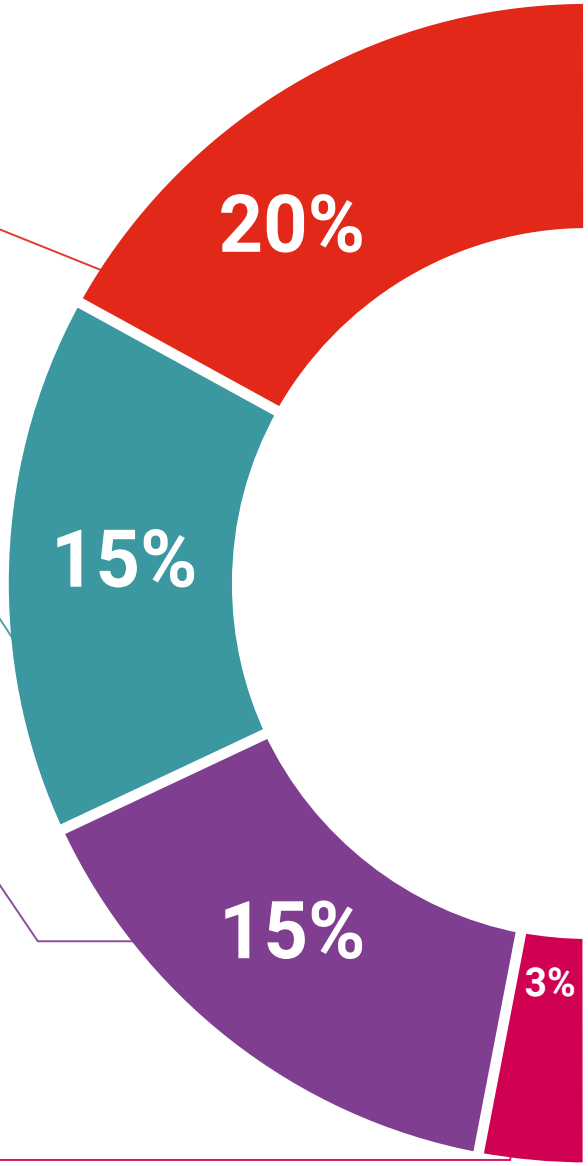
Interactive Summaries

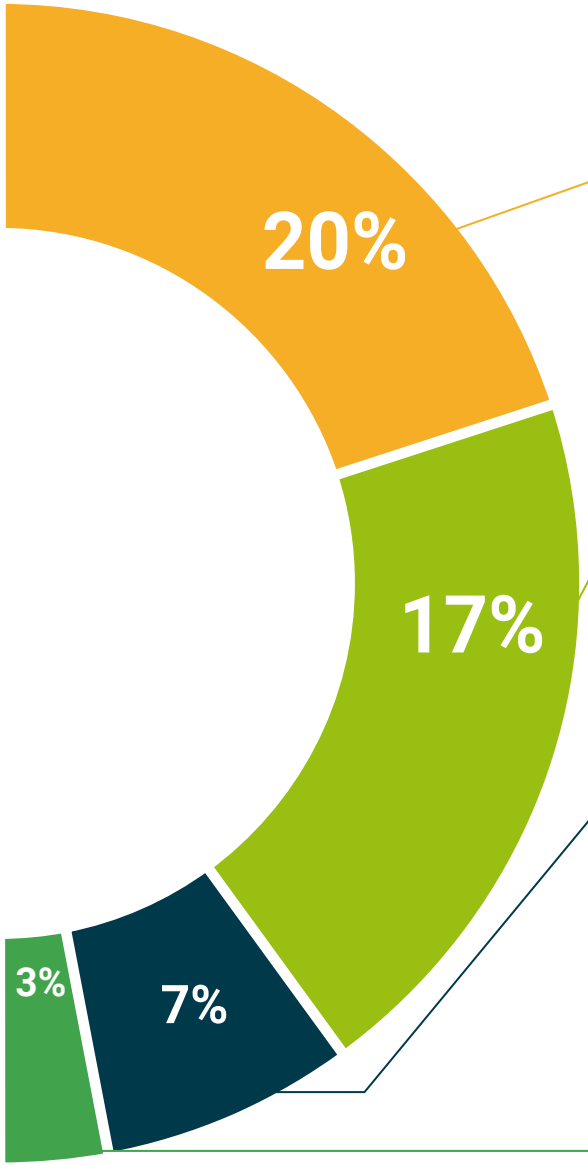
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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.

06

Certificate

The Postgraduate Certificate in Clinical Trials Coordination for Nursing guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate 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 Certificate in Clinical Trials Coordination for Nursing** 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 Certificate in Clinical Trials Coordination for Nursing**

Modality: **online**

Duration: **12 weeks**

Accreditation: **12 ECTS**


tech global university

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

Postgraduate Certificate in Clinical Trials Coordination for Nursing

This is a private qualification of 360 hour s of duration equivalent to 12 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 202 4

Dr. Pedro Navarro Illan a
Dean

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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