

# Postgraduate Certificate Clinical Trials Coordination





## Postgraduate Certificate Clinical Trials Coordination

- » Modality: online
- » Duration: 12 weeks
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

Website: [www.techtitute.com/us/medicine/postgraduate-certificate/clinical-trials-coordination](http://www.techtitute.com/us/medicine/postgraduate-certificate/clinical-trials-coordination)

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# 01

# Introduction

The coordination of a clinical trial is a fundamental part of the project, because if any process in the project fails, the entire research could be lost. As such, one could say that the researcher's file is like the "black box of the airplane" or the "logbook of a ship".





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*The goal of healthcare is to achieve a cure for diseases and a better quality of life for patients. Investing in research is important, but so is having specialized professionals”*

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. The investigator's file should contain all the documentation relating to the research team (curriculum vitae and other relevant documents showing the qualifications 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, and should therefore be kept in an appropriate manner.

To this end, this training will discuss the importance of the researcher's file, the documents it should contain, how they should be filed, how they should be completed and how long they should be kept.

On the other hand, in recent years the figure of clinical trial 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. In this sense, this program also analyzes the figure of the clinical trial coordinators, as well as their main responsibilities, the vital importance of the trial process and everything that surrounds it.

This **Postgraduate Certificate in Clinical Trials Coordination** contains the most complete and up-to-date educational program on the market. The most important features include:

- The development of practical 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 development
- New developments in Clinical Trials Coordination
- Practical exercises where self-assessment can be used 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 assignments
- Content that is accessible from any fixed or portable device with an internet connection



*Expand your knowledge through this Postgraduate Certificate in Clinical Trials Coordination 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 Coordination, you will obtain a qualification endorsed by TECH Technological University"*

The teaching staff includes professionals from the Health sector, who bring their experience to this training 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 training programmed to train in real situations.

This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise throughout the program. For this purpose, the professor will be assisted by an innovative interactive video system developed by renowned and experienced experts in the field of Clinical Trials Coordination.

*Do not hesitate to take this training 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.*



# 02 Objectives

The Postgraduate Certificate in Clinical Trials Coordination is aimed at facilitating the performance of the research professional with the latest advances and most innovative treatments in the sector.





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*Thanks to this program you will be able to specialize in Clinical Trials Coordination and learn about the latest advances in the field"*



## General Objectives

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- To train the student in the handling and management of the researcher's archive documentation, in accordance with current regulations, the Good Clinical Practice guidelines (GCP) and the International Conference on Harmonization (ICH)
- 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



*A unique, key, and decisive training experience to boost your professional development”*





## Specific Objectives

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- ◆ 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 bring the experience of their work to this training. Additionally, other recognized experts participate in its design and preparation, completing the program in an interdisciplinary manner.



A hand holding a small white vial in a laboratory setting. The background is blurred, showing what appears to be a laboratory bench with various pieces of equipment. The image is overlaid with a large blue geometric shape in the top right corner and a white geometric shape in the bottom left corner.

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

## Management



### Dr. Gallego Lago, Vicente

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

## Teachers

### D. Bravo Ortega, Carlos

- ♦ 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
- ♦ Coordinator of clinical trials in the Clinical Nephrology Service of the 12 de Octubre Hospital

### Dr. Dompablo Tobar, Mónica

- ♦ Degree in Psychology from the Autonomous University Madrid (2007)
- ♦ PhD in Psychology, Complutense University of Madrid (2017) Outstanding cum laude
- ♦ Researcher at the Psychiatry Department of the 12 de Octubre University Hospital. Since 2012

### Ms. Gómez Abecia, Sara

- ♦ Degree in Biology
- ♦ Project Manager on Clinical Investigation
- ♦ Master's Degree in Clinical Trials

### Ms. Jiménez Fernández, Paloma

- ♦ 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
- ♦ Coordinator of clinical trials in the Rheumatology Service of the 12 de Octubre Hospital



**Dr. Cano Armenteros, Montserrat**

- ♦ Master's Degree in Clinical Trials University of Seville
- ♦ Official Professional Master's Degree in Primary Care Research by the Miguel Hernández University of Alicante for the Doctorate Outstanding. Recognition 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 the field of Clinical Trials Coordination, with extensive experience and recognized prestige in the profession, backed by the volume of cases reviewed, studied and diagnosed, and with extensive knowledge of new technologies applied to the Coordination of Clinical Trials.





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*This Postgraduate Certificate in Clinical Trials Coordination contains the most complete and up-to-date scientific 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 Research Team
  - 1.2.1. CV
  - 1.2.2. Good Clinical Practice Certificate
  - 1.2.3. Specific Training Certificates
  - 1.2.4. Signed Statement of the Investigator, "Financial Disclosure"
  - 1.2.5. 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. Investigators Brochure (IB)
  - 1.7.2. Technical Data Sheets of the Drugs Under Study (If Marketed)
  - 1.7.3. Instructions for the Control of Specific Parameters (e.g. Temperature)
  - 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/Safety
  - 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. Protocol
  - 2.3.1. Primary and Secondary Objectives
    - 2.3.1.1. What Are They and Who Defines Them?
    - 2.3.1.2. Importance During the Course of the Clinical Trial
  - 2.3.2. Inclusion and Exclusion Criteria
    - 2.3.2.1. Inclusion Criteria
    - 2.3.2.2. Exclusion Criteria
    - 2.3.2.3. Example
  - 2.3.3. *Flowchart*
    - 2.3.3.1. Document and Explanation
  - 2.3.4. Concomitant Medication and Prohibited Medication
    - 2.3.4.1. Concomitant Drug
    - 2.3.4.2. Forbidden Medication
    - 2.3.4.3. Washout Periods
- 2.4. Documentation Required to Initiate Clinical Trial
  - 2.4.1. Curriculum of the Research Team
    - 2.4.1.1. Basic Notions of a Research Curriculum
    - 2.4.1.2. Good Clinical Practice Example
  - 2.4.2. Good Clinical Practice
    - 2.4.2.1. Origin of Good Clinical Practices
    - 2.4.2.2. How to Get Certified?
    - 2.4.2.3. Expiration

- 2.4.3. Suitability of the Research Team
  - 2.4.3.1. Who Signs the Document?
  - 2.4.3.2. Presentation to Ethics Committee
- 2.4.4. Suitability of Facilities
  - 2.4.4.1. Who Signs the Document?
  - 2.4.4.2. Ethical Committee Presentation
- 2.4.5. Calibration Certificates
  - 2.4.5.1. Calibration
  - 2.4.5.2. Calibration Equipment
  - 2.4.5.3. Valid Certifications
  - 2.4.5.4. Expiration
- 2.4.6. Other Training
  - 2.4.6.1. Necessary Certifications According Protocol
- 2.5. Main Functions Trial Coordinator
  - 2.5.1. Documentation Preparation
    - 2.5.1.1. Documentation Requested for Approval of the Study at the Center
  - 2.5.2. *Investigator Meeting*
    - 2.5.2.1. Importance
    - 2.5.2.2. Attendees
  - 2.5.3. Initiation Visit
    - 2.5.3.1. Duties of the Coordinator
    - 2.5.3.2. Functions of the Principal Investigator and Subinvestigators
    - 2.5.3.3. Promoter
    - 2.5.3.4. Monitor
  - 2.5.4. Monitoring Visit
    - 2.5.4.1. Preparation After a Monitoring Visit
    - 2.5.4.2. Functions During the Monitoring Visit
  - 2.5.5. End-Of-Study Visit
    - 2.5.5.1. Storage of the Researchers File
- 2.6. Relationship with the Patient
  - 2.6.1. Preparation of Visits
    - 2.6.1.1. Consents and Amendments
    - 2.6.1.2. Visit Window
    - 2.6.1.3. Identify the Responsibilities of the Investigation Team during the Visit
    - 2.6.1.4. Visit Calculator
    - 2.6.1.5. Preparation of Documentation to be Used During the Visit



- 2.6.2. Complementary Tests
  - 2.6.2.1. Analysis
  - 2.6.2.2. Chest X-Ray
  - 2.6.2.3. Electrocardiogram
- 2.6.3. Calendar of Visits
  - 2.6.3.1. Example
- 2.7. Samples
  - 2.7.1. Equipment and Materials Necessary
    - 2.7.1.1. Centrifuge
    - 2.7.1.2. Incubator
    - 2.7.1.3. Refrigerators
  - 2.7.2. Processing of Samples
    - 2.7.2.1. General Procedure
    - 2.7.2.2. Example
  - 2.7.3. Laboratory Kits
    - 2.7.3.1. What are they?
    - 2.7.3.2. Expiration
  - 2.7.4. Shipment of Samples
    - 2.7.4.1. Sample Storage
    - 2.7.4.2. Ambient Temperature Shipment
    - 2.7.4.3. Shipping Frozen Samples
- 2.8. Data Collection Notebooks
  - 2.8.1. What Is It?
    - 2.8.1.1. Types of Notebooks
    - 2.8.1.2. Paper Notebook
    - 2.8.1.3. Electronic Notebook
    - 2.8.1.4. Specific Notebooks According to Protocol
  - 2.8.2. How To Complete It?
    - 2.8.2.1. Example
  - 2.8.3. Query
    - 2.8.3.1. What Is A Query?
    - 2.8.3.2. Resolution Time
    - 2.8.3.3. Who Can Open a Query?
- 2.9. Randomization Systems
  - 2.9.1. What Is It?
  - 2.9.2. Types of IWRS:
    - 2.9.2.1. Telephonics
    - 2.9.2.2. Electronics
  - 2.9.3. Researcher Responsibilities vs. Research Team Responsibilities
    - 2.9.3.1. Screening
    - 2.9.3.2. Randomization
    - 2.9.3.3. Scheduled Visits
    - 2.9.3.4. *Unscheduled Visits*
    - 2.9.3.5. Blinding Opening
  - 2.9.4. Medication
    - 2.9.4.1. Who Receives the Medication?
    - 2.9.4.2. Drug Traceability
  - 2.9.5. Return of Medication
    - 2.9.5.1. Functions of the Research Team in the Return of Medication
- 2.10. Biological Treatments
  - 2.10.1. Coordination of Clinical Trials with Biologics
    - 2.10.1.1. Biological Treatments
    - 2.10.1.2. Types of Treatment
  - 2.10.2. Types of Studies
    - 2.10.2.1. Biological Criteria Placebo
    - 2.10.2.2. Biological Criteria Biological Criteria
  - 2.10.3. Biological Management
    - 2.10.3.1. Administration
    - 2.10.3.2. Traceability
  - 2.10.4. Rheumatic Diseases
    - 2.10.4.1. Rheumatoid Arthritis
    - 2.10.4.2. Psoriatic Arthritis
    - 2.10.4.3. Lupus
    - 2.10.4.4. Scleroderma

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.



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*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, 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. 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, trying to recreate the real conditions in the physician's professional practice.



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*Did you know that this method was developed in 1912, at Harvard, for law students? The case method consisted of presenting students with real-life, complex situations for them to make decisions and justify their decisions on how to solve them. In 1924, Harvard adopted it as a standard teaching method”*

The effectiveness of the method is justified by four fundamental achievements:

1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
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. 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 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.

*Professionals 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 250,000 physicians have been trained with unprecedented success in all clinical specialties regardless of surgical load. 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.

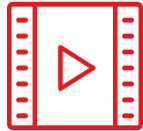
*Relearning will allow you to learn with less effort and better performance, involving you more in your specialization, developing a critical mindset, defending arguments, and contrasting opinions: a direct equation to success.*

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 highly 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.



#### Surgical Techniques and Procedures on Video

TECH introduces students to the latest techniques, the latest educational advances and 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 the videos as many times as you like.



#### Interactive Summaries

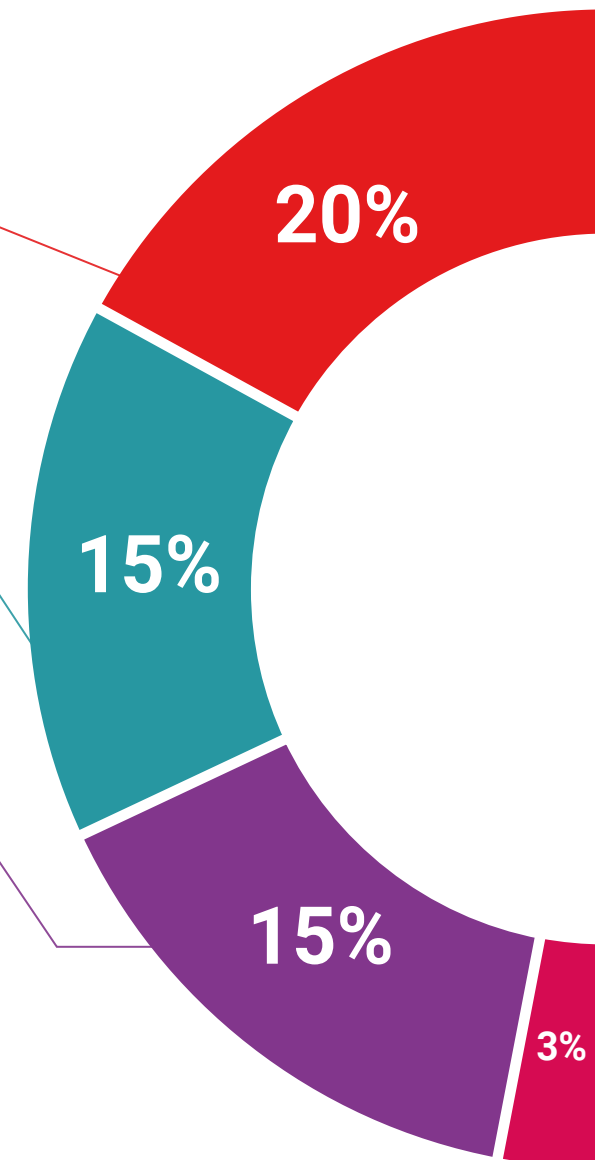
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

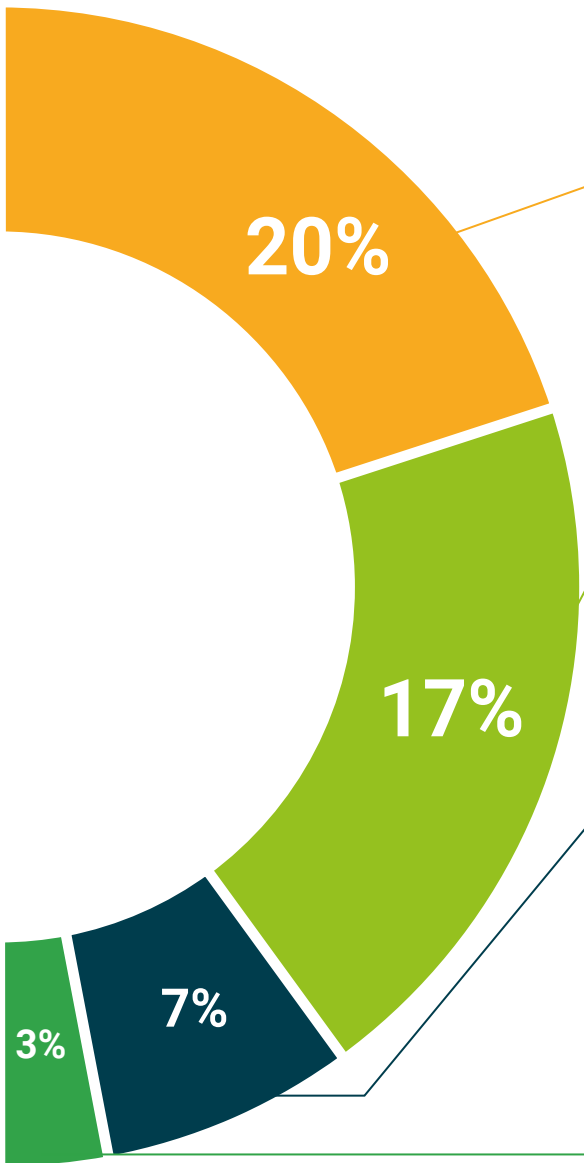
This exclusive educational system for presenting multimedia content was awarded by Microsoft as a "European Success Story".



#### 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 on the usefulness of learning by observing experts. The system known as 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 guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate issued by TECH Technological University.



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

This **Postgraduate Certificate in Clinical Trials Coordination** 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 Coordination**

Official N° 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.



future

health

confidence people

education information tutors

guarantee accreditation teaching

institutions technology learning

community commitment

personalized service innovation

knowledge present

online training

development languages

virtual classroom

**tech** technological  
university

**Postgraduate Certificate**  
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