

# Postgraduate Diploma Clinical Trials





## Postgraduate Diploma Clinical Trials

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

Website: [www.techtitute.com/pk/medicine/postgraduate-diploma/postgraduate-diploma-clinical-trials](http://www.techtitute.com/pk/medicine/postgraduate-diploma/postgraduate-diploma-clinical-trials)

# Index

01

Introduction

---

*p. 4*

02

Objectives

---

*p. 8*

03

Course Management

---

*p. 12*

04

Structure and Content

---

*p. 16*

05

Methodology

---

*p. 24*

06

Certificate

---

*p. 32*

# 01

# Introduction

Clinical trials are the necessary formula for finding new treatments that help improve the quality of life of patients. These investigations include the participation of individuals, so it is of vital importance that they comply with all existing regulations on the subject and with qualified professionals in the field.



“

*The current importance of pharmacological research makes this Postgraduate Diploma an essential training for professionals in the sector”*

Increased investment in research in the healthcare field to improve the quality of life of patients means that more and more professionals specialized in this field are needed. Hence the importance of broadening specialization in all research areas.

In this way, students will delve into the study of preclinical drug research, i.e., from the discovery of a molecule with therapeutic activity until it is marketed. Another very important part of this process is to know how to communicate new discoveries, which will allow further research in this field and promote its use.

Additionally, the essential concepts to support the methodological and semantic complexity of clinical trials are addressed. As such, the categories according to which clinical trials are classified are established in order to delve into different types of clinical trials, such as Phase I trials, due to their great complexity, and post-marketing research of investigational products, due to their enormous involvement in pharmacovigilance processes.

It should be noted that, within the clinical trial process, the figure of the pharmacists is of great importance, since they perform a series of essential tasks and responsibilities that guarantee the quality of the investigational drug samples.

All of the above makes this Postgraduate Diploma one of the most up to date and complete programs on the market, and offers the healthcare professional a general overview of clinical trials, but with special and particular cases in which these investigations have proved to be extremely important and beneficial.

This **Postgraduate Diploma in Clinical Trials** 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 development
- ♦ 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 assignments
- ♦ Content that is accessible from any fixed or portable device with an internet connection



*Expand your knowledge through this Postgraduate Diploma in Clinical Trials that will allow you to specialize until you achieve excellence in this field"*

“

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

Its teaching staff includes professionals belonging to the healthcare field, who bring to this program the experience of their work, as well as renowned specialists from prestigious universities and reference societies.

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 learning 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 scientific program. For this purpose, the professor will be assisted by an innovative interactive video system created by renowned and experienced experts in the field of clinical trials.

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

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



# 02 Objectives

The Postgraduate Diploma in Clinical Trials is aimed at facilitating the performance of the research professional with the latest advances in the sector.







“

*Thanks to this Postgraduate Diploma you will be able to specialize in Clinical Trials and learn about the latest advances in the field”*



## General Objectives

- Establish the phases involved in the development of a new drug
- Analyze the steps prior to the development of a clinical trial (preclinical research)
- Examine how a drug is introduced into the market after the clinical trial has been conducted
- Establish the basic structure of a clinical trial
- Justify the difference between different types of clinical trials
- Compile the essential documents and procedures within a clinical trial
- Develop the clinical trial drug circuit from the point of view of the Pharmacy Service
- Analyze a clinical trial in the setting of a Urology Department
- Establish the specific characteristics of clinical trials in children and adolescents





## Specific Objectives

---

### Module 1. Drug research and development

- ♦ Explain the pharmacokinetic processes that a drug undergoes in the organism
- ♦ Identify the legislation that regulates each of the steps in the development and authorization of a drug
- ♦ Define the specific regulation of some drugs (biosimilars, advanced therapies)
- ♦ Define the use in special situations and their types
- ♦ Examine the process of financing a drug
- ♦ Specify strategies for the dissemination of research results
- ♦ Present how to read scientific information critically
- ♦ Compile sources of information on drugs and their types

### Module 2. Clinical Trials (I)

- ♦ Establish the types of clinical trials and standards of good clinical practice
- ♦ Specify the processes of authorization and distinction of drugs and medical devices in research
- ♦ Analyze the evolutionary process of drug research development
- ♦ Specify strategies for developing a safety surveillance plan for marketed drugs
- ♦ Substantiate the necessary requirements for the initiation of research with drugs in humans
- ♦ Establish the elements of a clinical trial research protocol
- ♦ Substantiate the difference between inferiority and non-inferiority clinical trials
- ♦ Compile the essential documents and procedures within a clinical trial
- ♦ Specify the utility and learn the use of data collection notebooks (DCNs)

- ♦ Analyze the variety of avenues for the development and funding of non-commercial research
- ♦ Disclose the types of fraud committed in clinical trials research

### Module 3. Clinical Trials (II)

- ♦ Specify the different activities related to sample management (reception, dispensing, custody, etc.) in which the Pharmacy team is involved
- ♦ Establish the procedures and techniques involved in the safe handling of samples during their preparation
- ♦ Analyze the development of a clinical trial through the vision and participation of the hospital pharmacist
- ♦ Compile the specific characteristics of clinical trials in children and adolescents from a legal point of view
- ♦ Detail informed consent
- ♦ Know the physiological differences between children and adults



*An intensive program that will allow you to become a specialist in Clinical Trials in a short period of time and with the greatest flexibility"*

03

# Course Management

The scientific program includes in its teaching staff leading experts in research and health, who bring the experience of their work to this program. Additionally, other recognized experts participate in its design and elaboration, completing the program in an interdisciplinary manner.





“

*The leading experts in Clinical Trials  
have joined forces 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
- Resident Internal Pharmacist of the Pharmacy Service of the "12 de Octubre" Hospital". Madrid

## Professors

### Ms. Díaz García, Marta

- ♦ Degree in Social and Cultural Anthropology from the UCM, Diploma in Nursing from the University of Extremadura
- ♦ Master's Degree in Health Care Research at UCM
- ♦ Master's Degree in Pharmacology from the Distance University of Valencia
- ♦ Nurse of Pneumology, Endocrinology and Rheumatology at the 12 de Octubre University Hospital in Madrid
- ♦ Researcher in FIS project "Circadian health in patients admitted to intensive care and hospitalization units"

### D. Moreno Muñoz, Guillermo

- ♦ Degree in Nursing from the Complutense University of Madrid (UCM)
- ♦ Master's Degree in Health Care Research, UCM
- ♦ Expert in Nurse Prescription by the Distance Learning University of Madrid
- ♦ Coordinator of Clinical Trials and Observational Studies in the Cardiology Intensive Care Unit of the Cardiology Service of the 12 de Octubre Hospital
- ♦ Collaborating Professor of Pharmacology and Nurse Prescription of the Department of Nursing, Physiotherapy and Podiatry of the UCM

**Ms. Ochoa Parra, Nuria**

- ◆ Degree in Pharmacy from the Complutense University of Madrid
- ◆ Master's Degree in Clinical Trials from the University of Sevilla
- ◆ Dr. candidate from the University of Granada
- ◆ Coordinator of clinical trials and observational studies in the Multidisciplinary Unit of Pulmonary Hypertension of the Cardiology Department of the 12 de Octubre Hospital

**Dr. Valtueña Murillo, Andrea**

- ◆ Pharmaceutical Industry. Community pharmacy. Hospital Pharmacy.
- ◆ Master's Degree in Pharmaceutical and Parapharmaceutical Industry at CESIF | November 2018 - November 2019
- ◆ Degree in Pharmacy from the Complutense University Madrid | 2013– 2018

**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

**Mr. Sánchez Ostos, Manuel**

- ◆ Study Coordinator Clinicas Trials, IMIBIC
- ◆ Master's Degree in Clinical Trial Monitoring and Pharmaceutical Development, Nebrija University (Madrid)
- ◆ Master's Degree in Biotechnology. University of Córdoba
- ◆ Master's Degree in Teacher Training. University of Córdoba
- ◆ Degree in Biology. University of Córdoba

# 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 Postgraduate Diploma in Clinical Trials contains the most complete and up to date scientific program on the market”*

## Module 1. Drug research and development

- 1.1. Development of New Drugs
  - 1.1.1. Introduction
  - 1.1.2. Development Phases of New Drugs
  - 1.1.3. Discovery Phase
  - 1.1.4. Preclinical Phase
  - 1.1.5. Clinical Phase
  - 1.1.6. Approval and Registration
- 1.2. Discovery of an Active Substance
  - 1.2.1. Pharmacology
  - 1.2.2. Seeding Trials
  - 1.2.3. Pharmacological Interactions
- 1.3. Pharmacokinetics
  - 1.3.1. Methods of Analysis
  - 1.3.2. Absorption
  - 1.3.3. Distribution
  - 1.3.4. Metabolism
  - 1.3.5. Excretion
- 1.4. Toxicology
  - 1.4.1. Single Dose Toxicity
  - 1.4.2. Repeated Dose Toxicity
  - 1.4.3. Toxicokinetics
  - 1.4.4. Carcinogenicity
  - 1.4.5. Genotoxicity
  - 1.4.6. Reproductive Toxicity
  - 1.4.7. Tolerance
  - 1.4.8. Dependency
- 1.5. Regulation of Drugs for Human Use
  - 1.5.1. Introduction
  - 1.5.2. Authorization Procedures
  - 1.5.3. How a Drug is Evaluated: Authorization Dossier
  - 1.5.4. Technical Data Sheet, Package Leaflet and EPAR
  - 1.5.5. Conclusions

- 1.6. Pharmacovigilance
  - 1.6.1. Pharmacovigilance in Development
  - 1.6.2. Pharmacovigilance in Marketing Authorization
  - 1.6.3. Post-authorization Pharmacovigilance
- 1.7. Uses in Special Situations
  - 1.7.1. Introduction
  - 1.7.2. Regulations
  - 1.7.3. Examples:
- 1.8. From Authorization to Commercialization
  - 1.8.1. Introduction
  - 1.8.2. Drug Financing
  - 1.8.3. Therapeutic Positioning Reports
- 1.9. Special Forms of Regulation
  - 1.9.1. Advanced Therapies
  - 1.9.2. Accelerated Approval
  - 1.9.3. Biosimilars
  - 1.9.4. Conditional Approval
  - 1.9.5. Orphan Drugs
- 1.10. Dissemination of Research
  - 1.10.1. Scientific Article
  - 1.10.2. Types of Scientific Articles
  - 1.10.3. Quality of Research *Checklist*
  - 1.10.4. Drug Information Sources

## Module 2. Clinical Trials (I)

- 2.1. Clinical Trials. Fundamental Concepts I
  - 2.1.1. Introduction
  - 2.1.2. Definition of clinical trial (CT)
  - 2.1.3. History of Clinical Trials
  - 2.1.4. Clinical Research
  - 2.1.5. Parties Involved in CTs
  - 2.1.6. Conclusions



- 2.2. Clinical Trials. Fundamental Concepts II
  - 2.2.1. Standards of Good Clinical Practice
  - 2.2.2. Clinical Trial Protocol and Annexes
  - 2.2.3. Pharmacoeconomic Assessment
  - 2.2.4. Aspects that Could Be Improved in Clinical Trials
- 2.3. Clinical Trials Classification
  - 2.3.1. Clinical Trials Purpose
  - 2.3.2. Clinical Trials According to the Scope of Research
  - 2.3.3. Clinical Trials Methodology
  - 2.3.4. Treatment Groups
  - 2.3.5. Clinical Trials Masking
  - 2.3.6. Treatment Assignment
- 2.4. Phase I Clinical Trials
  - 2.4.1. Introduction
  - 2.4.2. Phase I Clinical Trials Characteristics
  - 2.4.3. Phase I Clinical Trials Design
    - 2.4.3.1. Single Dose Trials
    - 2.4.3.2. Multiple Dose Trials
    - 2.4.3.3. Pharmacodynamic Studies
    - 2.4.3.4. Pharmacokinetic Studies
    - 2.4.3.5. Bioavailability and Bioequivalence Studies
  - 2.4.4. Phase I Units
  - 2.4.5. Conclusions
- 2.5. Post-Authorization Studies Types of Design and Procedures
  - 2.5.1. Concept
  - 2.5.2. Justification and Objectives
  - 2.5.3. Medical history
  - 2.5.4. Classification According to Objectives and Design
    - 2.5.4.1. Security/safety
    - 2.5.4.2. Drug Utilization Studies (DUS)
    - 2.5.4.3. Pharmacoeconomic Studies
  - 2.5.5. Administrative Procedures for Observational Post-Authorization Studies (PAS)
  - 2.5.6. Other Information of Interest
  - 2.5.7. Conclusions

- 2.6. Equivalence and Non-Inferiority Cts (I)
  - 2.6.1. Equivalence and Non-Inferiority Clinical Trials
    - 2.6.1.1. Introduction
    - 2.6.1.2. Justification
    - 2.6.1.3. Therapeutic Equivalence and Bioequivalence
    - 2.6.1.4. Concept of Therapeutic Equivalence and Non-Inferiority
    - 2.6.1.5. Objectives
    - 2.6.1.6. Basic Statistical Aspects
    - 2.6.1.7. Intermediate Data Tracking
    - 2.6.1.8. Quality of Equivalence and Non-Inferiority RCTs
    - 2.6.1.9. Ethical Aspects
    - 2.6.1.10. Post-Equivalence
  - 2.6.2. Conclusions
- 2.7. Equivalence and Non-Inferiority CTs (II)
  - 2.7.1. Therapeutic Equivalence in Clinical Practice
    - 2.7.1.1. Level 1: Direct Trials Between 2 Drugs, with Equivalence or Non-Inferiority Design
    - 2.7.1.2. Level 2: Direct Trials Between 2 Drugs, with Statistically Significant Differences, but without Clinical Relevance
    - 2.7.1.3. Level 3: Not Statistically Significant Trials
    - 2.7.1.4. Level 4: Different Trials vs. a Third Common Denominator
    - 2.7.1.5. Level 5: Trials vs. Different Comparators and Observational Studies
    - 2.7.1.6. Supporting Documentation: Reviews, Clinical Practice Guidelines, Recommendations, Expert Opinion, Clinical Judgment
  - 2.7.2. Conclusions
- 2.8. Guidelines for the Development of a Clinical Trial Protocol
  - 2.8.1. Summary
  - 2.8.2. Index
  - 2.8.3. General Information
  - 2.8.4. Justification
  - 2.8.5. Hypothesis and Objectives of the Trial
  - 2.8.6. Trial Design
  - 2.8.7. Selection and Withdrawal of Subjects
  - 2.8.8. Treatment of Subjects
  - 2.8.9. Efficacy Assessment
  - 2.8.10. Safety Assessment
    - 2.8.10.1. Adverse Events
    - 2.8.10.2. Adverse Events Management
    - 2.8.10.3. Adverse Events Notification
  - 2.8.11. Statistics
  - 2.8.12. Ethical Aspects
  - 2.8.13. Information and Consent
  - 2.8.14. Financing and Insurance
  - 2.8.15. Publication Policy
  - 2.8.16. Conclusions
- 2.9. Non-Protocol Administrative Aspects of Clinical Trials
  - 2.9.1. Documentation Required for the Start of the Trial
  - 2.9.2. Subject Identification, Recruitment and Selection Records
  - 2.9.3. Source Documents
  - 2.9.4. Data Collection Notebooks (DCNs)
  - 2.9.5. Monitoring
  - 2.9.6. Conclusions
- 2.10. Data Collection Notebooks (DCNs)
  - 2.10.1. Definition
  - 2.10.2. Function
  - 2.10.3. Importance and Confidentiality
  - 2.10.4. Types of Data Collection Notebooks
  - 2.10.5. Elaboration of the Data Collection Notebook
    - 2.10.5.1. Types of Data
    - 2.10.5.2. Order
    - 2.10.5.3. Graphic Design
    - 2.10.5.4. Filling in the Data
    - 2.10.5.5. Recommendations
  - 2.10.6. Conclusions

**Module 3. Clinical Trials (II)**

- 3.1. Involvement of the Pharmacy Service in the Realization of Clinical Trials Sample Management (I)
  - 3.1.1. Manufacturing/Importation
  - 3.1.2. Acquisition
  - 3.1.3. Reception
    - 3.1.3.1. Shipment Verification
    - 3.1.3.2. Label Checking
    - 3.1.3.3. Shipment Confirmation
    - 3.1.3.4. Entry Registration
  - 3.1.4. Custody/Storage
    - 3.1.4.1. Expiration Control
    - 3.1.4.2. Relabeling
    - 3.1.4.3. Temperature Control
  - 3.1.5. Sample Prescription Request
  - 3.1.6. Medical Prescription Validation
  - 3.1.7. Dispensing
    - 3.1.7.1. Dispensing Procedure
    - 3.1.7.2. Checking Storage Conditions and Expiration Date
    - 3.1.7.3. Dispensing Act
    - 3.1.7.4. CheckOut
- 3.2. Involvement of the Pharmacy Service in the Realization of Clinical Trials Sample Management (II)
  - 3.2.1. Preparation/Conditioning
    - 3.2.1.1. Introduction
    - 3.2.1.2. Current Legislation Regulations
    - 3.2.1.3. Exposure Routes and Handler Protection
    - 3.2.1.4. Centralized Preparation Unit
    - 3.2.1.5. Installations
    - 3.2.1.6. Individual Protection Equipment
    - 3.2.1.7. Closed Systems and Handling Equipment
    - 3.2.1.8. Technical Aspects of Preparation
    - 3.2.1.9. Cleaning Standards
    - 3.2.1.10. Waste Treatment in the Preparation Area
    - 3.2.1.11. Actions in Case of Spill and/or Accidental Exposure

- 3.2.2. Accounting/Inventory
- 3.2.3. Return/Destruction
- 3.2.4. Reports and Statistics
- 3.3. Involvement of the Pharmacy Service in the Realization of Clinical Trials Role of the Pharmacist
  - 3.3.1. Visits Manager
    - 3.3.1.1. Preselection Visit
    - 3.3.1.2. Initiation Visit
    - 3.3.1.3. Monitoring Visit
    - 3.3.1.4. Audits and Inspections
    - 3.3.1.5. Closing Visit
    - 3.3.1.6. Archive
  - 3.3.2. Member of the Ethics Committee
  - 3.3.3. Clinical-Research Activity
  - 3.3.4. Teaching Activity
  - 3.3.5. Process Auditor
    - 3.3.5.1. Situation of the Hospital Pharmacy Service (HPS) and CT Units
  - 3.3.6. Complexity of CTs
  - 3.3.7. CTs as Sustainability the Health Care System
- 3.4. Clinical Trials in the Hospital Urology Service (I)
  - 3.4.1. Basic Principles of Urologic Pathology Related to Clinical Trials
    - 3.4.1.1. Non-Oncologic Urologic Pathology
      - 3.4.1.1.1. Benign Prostatic Hypertrophy
      - 3.4.1.1.2. Urinary Infection
      - 3.4.1.1.3. Erectile Dysfunction
      - 3.4.1.1.4. Hypogonadisms
    - 3.4.1.2. Oncologic Urologic Pathology
      - 3.4.1.2.1. Bladder Tumors
      - 3.4.1.2.2. Prostate Cancer

- 3.4.2. Background and Rationale for Clinical Trials in Urology
  - 3.4.2.1. Foundation
  - 3.4.2.2. Medical history
  - 3.4.2.3. Placebo Rationale
  - 3.4.2.4. Name and Mechanism of Action of the Investigational Product
  - 3.4.2.5. Conclusions from Previous Studies in Humans
  - 3.4.2.6. Benefits and Risks of Study Medication
    - 3.4.2.6.1. Dosage and Administration
    - 3.4.2.6.2. Medication Management Guidelines at Home
    - 3.4.2.6.3. Overdosage/Infradosification
  - 3.4.2.7. Double-Blind/Open Study
- 3.4.3. Objectives and Assessment Criteria of the Study
  - 3.4.3.1. Study Objectives
    - 3.4.3.1.1. Safety Objective
    - 3.4.3.1.2. Exploratory Objectives
  - 3.4.3.2. Assessment Criteria of the Study
    - 3.4.3.2.1. Primary Efficacy Endpoints
    - 3.4.3.2.2. Secondary Efficacy Assessment Criteria
- 3.4.4. Research Plan
- 3.4.5. Preselection of Candidates for Clinical Trials
- 3.4.6. Study Procedures by Period
- 3.5. Clinical Trials in the Urology Service (II)
  - 3.5.1. Patient Retention
    - 3.5.1.1. Post-Treatment Monitoring Visits
    - 3.5.1.2. Longterm Monitoring Visits
  - 3.5.2. Safety Assessments
    - 3.5.2.1. Adverse Effects Management
    - 3.5.2.2. SAEs Management
    - 3.5.2.3. Assigned Treatment Emergency Unblinding
  - 3.5.3. Study Administration
    - 3.5.3.1. Dose-Limiting Toxicities
    - 3.5.3.2. Interrupting the Treatment



- 3.5.4. Researchers Obligations
  - 3.5.4.1. Regulatory Compliance and Ethics
  - 3.5.4.2. Informed Consent
- 3.5.5. Quality Control and Compliance
  - 3.5.5.1. Authorization of Subjects Protected Health Information
  - 3.5.5.2. Retention of Study Records and Files
  - 3.5.5.3. Data Collection Notebooks
  - 3.5.5.4. Protocol Amendments
- 3.5.6. Conclusions
- 3.6. Approval of a Clinical Trial to the Urology Service Steps to Follow Trial Conclusion
  - 3.6.1. *Feasibility*
  - 3.6.2. Preselection Visit
    - 3.6.2.1. Main Investigators Role
    - 3.6.2.2. Logistics and Hospital Resources
  - 3.6.3. Documentation
  - 3.6.4. Initiation Visit
  - 3.6.5. Source Document
    - 3.6.5.1. Patient's Clinical History
    - 3.6.5.2. Hospital Reports
  - 3.6.6. *Vendors*
    - 3.6.6.1. Interactive Web Response Systems (IWRS)
    - 3.6.6.2. Electronic Case Report Form (eCRF)
    - 3.6.6.3. Images
    - 3.6.6.4. Suspected Unexpected Serious Adverse Reactions (SUSARs)
    - 3.6.6.4. Accounting
  - 3.6.7. Training
  - 3.6.8. Delegation of Functions
  - 3.6.9. Visit to Other Services Involved
  - 3.6.10. Closing the Trial
- 3.7. General Information about Clinical Trials in Children and Adolescents
  - 3.7.1. History of Clinical Trials in Children
  - 3.7.2. Informed Consent
- 3.8. Clinical Trials in Adolescents
  - 3.8.1. Adolescent Clinical Trials Practical Features
  - 3.8.2. New Approaches to Adolescent Trials
- 3.9. Clinical Trials in Children
  - 3.9.1. Specific Physiological Characteristics of the Child
  - 3.9.2. Children Clinical Trials
- 3.10. Clinical Trials in Neonatal
  - 3.10.1. Specific Physiological Characteristics the Neonatal
  - 3.10.2. Neonatal Clinical Trials



*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 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.

“

*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 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.



#### 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 Diploma in Clinical Trials guarantees students, in addition to the most rigorous and up to date education, access to a Postgraduate Diploma issued by TECH Technological University.







“

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

This **Postgraduate Diploma in Clinical Trials** 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 Diploma** issued by **TECH Technological University** via tracked delivery\*.

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

**Title: Postgraduate Diploma in Clinical Trials**

**Official N° of hours: 450 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.

future  
health confidence people  
education information tutors  
guarantee accreditation teaching  
institutions technology learning  
community commitment  
personalized service innovation  
knowledge present quality  
development language  
virtual classroom

**tech** technological  
university

## Postgraduate Diploma Clinical Trials

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

# Postgraduate Diploma Clinical Trials

