

# Postgraduate Diploma

## Research and Development of Medicines





## Postgraduate Diploma Research and Development of Medicines

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Global University
- » Credits: 18 ECTS
- » Schedule: at your own pace
- » Exams: online

Website: [www.techtute.com/us/pharmacy/postgraduate-diploma/postgraduate-diploma-research-development-medicines](http://www.techtute.com/us/pharmacy/postgraduate-diploma/postgraduate-diploma-research-development-medicines)

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# 01

# Introduction

The development of new drugs is a sector in constant growth, since investments in this field are increasing, due to the growing awareness, both by public and private institutions, of the importance of research to improve the health and quality of life of society as a whole. Therefore, with this program we want to specialize pharmacists in the field of Research and Development of Medicines, to increase their education and give a boost to their career.





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*Increase your education in the field of drug development, a fast-growing industry that demands specialized pharmacists”*



Pharmacists who wish to develop their professional work in the field of drug development will find in this Postgraduate Diploma the most complete specialization in the market. All this in an innovative program designed by a team of professionals with years of research and teaching experience.

Specifically, in this Postgraduate Diploma, students will focus on the study of preclinical drug research, as well as statistics, which is essential to reach reasonable and accurate conclusions. All aspects related to drug research and development will be available to pharmacists in this Postgraduate Diploma, in which they will also find the most up to date regulations on the subject.

And all this with an innovative methodology that will allow a contextual study, supported by a multitude of practical cases, so that the learning of all the theoretical content is more understandable. Thus, after completing this Postgraduate Diploma, the student will be trained to comply with the ethical standards in Clinical Trials, to ensure compliance with the standards of validity and reliability for the data obtained and the correct design of Clinical Trials.

This training program has the advantage of being offered in a 100% online format, so the student will not have any schedule obligations or need to move to a physical space, being able to organize by themselves where and when to study. A self-management of your time that will allow you to combine your studies with the rest of your daily obligations.

This **Postgraduate Diploma in Research and Development of Medicines** contains the most complete and up-to-date scientific program on the market. The most important features of the program include:

- ♦ The development of case studies presented by experts in the Research and Development of Medicines
- ♦ 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
- ♦ News on Research and Development of Medicines
- ♦ Practical exercises where self-assessment can be used to improve learning
- ♦ Special emphasis on innovative methodologies in Research and Development of Medicines
- ♦ 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



*Broaden your knowledge through this Postgraduate Diploma in Research and Development of Medicines that will allow you to specialize until you achieve excellence in this field"*

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*This Postgraduate Diploma is the best investment you can make in the selection of a refresher program for two reasons: in addition to updating your knowledge in Research and Development of Medicines, you will obtain a degree endorsed by TECH Global University”*

The teaching staff includes professionals from the engineering sector, who bring their experience to this specialization 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. To do so, the nurse will be assisted by an innovative interactive video system created by renowned and experienced experts in the field of Research and Development of Medicines.

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

*This Postgraduate Diploma 100% online and will enable you to combine your studies while increasing your knowledge in this field.*



# 02 Objectives

The Postgraduate Diploma in Research and Development of Medicines is aimed at facilitating the performance of the research professional with the latest advances in the sector.





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*Thanks to this Postgraduate Diploma, you will be able to specialize in Research and Development of Medicines, and learn about the latest advances in the field"*



## General Objectives

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- ♦ 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
- ♦ Develop knowledge that provides a basis or opportunity to be original in the development and/or application of ideas, often in a research context
- ♦ Apply the acquired knowledge and resolution skills in the development of protocols
- ♦ Structure statistical methods and techniques
- ♦ Communicate and transmit statistical results through the preparation of different types of reports, using terminology specific to the fields of application
- ♦ Compile, identify and select sources of public biomedical information, from international agencies and scientific organizations, on the study and dynamics of populations
- ♦ Analyze the scientific method and work on skills in the management of information sources, bibliography, protocol elaboration and other aspects considered necessary for the design, execution and critical assessment
- ♦ Demonstrate logical thinking and structured reasoning in determining the appropriate statistical technique
- ♦ Analyze universal ethical principles
- ♦ Define the current legislation on research with drugs and medical devices in general and that which regulates clinical trials in particular
- ♦ Compile the rights and duties of the different parties involved in clinical trials



## Specific Objectives

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### Module 1. Research and Development of Medicines

- ♦ 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. Biostatistics

- ♦ Identify and incorporate in the advanced mathematical model, which represents the experimental situation, those random factors involved in a high-level biosanitary study
- ♦ Design, collect and clean a data set for subsequent statistical analysis
- ♦ Identify the appropriate method for determining the sample size
- ♦ Distinguish between different types of studies and choose the most appropriate type of design according to the research objective
- ♦ Communicate and transmit statistical results correctly, through the preparation of reports





### Module 3. Bioethics and Regulations

- ◆ Acquire an ethical and social commitment
- ◆ Develop the basic principles and ethical norms that regulate biomedical research
- ◆ Substantiate the justification of bioethics in the field of research
- ◆ Establish the application of ethical principles in the selection of participants
- ◆ Specify the principles of the benefit-risk balance in research with drugs and medical devices
- ◆ Define informed consent and patient information sheet
- ◆ Analyze the guarantees of patient safety in clinical trials
- ◆ Establish Good Clinical Practice Standards and their correct application
- ◆ Analyze the current European legislation on clinical trials
- ◆ Establish procedures for the authorization of drugs and medical devices
- ◆ Present the role and structure of clinical research ethics committees

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*An intensive course that will allow you to become a Postgraduate Diploma in Research and Development of Medicines in a short period of time and with the greatest flexibility”*

03

# Course Management

The program's teaching staff includes leading experts in research and healthcare, who bring their work experience to this specialization. Additionally, other recognized experts have participated in its design and preparation, complementing the program in an interdisciplinary manner.







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*The leading experts in Research and Development of Medicines have come together to show 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 (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". Madrid

## Teachers

### Ms. Benito Zafra, Ana

- ♦ Degree in Biology from the Autonomous University Madrid (2017).
- ♦ Master's Degree in Biochemistry, Molecular Biology and Biomedicine from the Complutense University of Madrid (2018).
- ♦ Coordinator of clinical trials and projects in the Heart Failure Unit at the Cardiology Department of the 12 de Octubre Hospital of Madrid.

### Ms. Bermejo Plaza, Laura

- ♦ Degree in Nursing from the Complutense University of Madrid.
- ♦ Coordinator of Clinical Trials at the HIV Unit of the 12 de Octubre University Hospital of Madrid.

### 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, 12 de Octubre Hospital.

### Ms. De Torres Pérez, Diana

- ♦ 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).



**Ms. Díaz García, Marta**

- ◆ Degree in Social and Cultural Anthropology from the UCM, Certificate 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"

**Dr Dompablo Tobar, Mónica**

- ◆ Degree in Psychology from the Autonomous University Madrid (2007)
- ◆ Doctorate in Psychology from the Complutense University of Madrid (2017). Outstanding Cum Laude award
- ◆ 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**

- ◆ Degree 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.

**Ms. Martín-Arriscado Arroba, Cristina**

- ♦ Biostatistics at the Research and Scientific Support Unit of the 12 de Octubre University Hospital (i+12) and the Clinical Research Units and Clinical Trials Platform (SCReN).
- ♦ Member of the Drug Research Ethics Committee of the 12 de Octubre University Hospital.

**D. Moreno Muñoz, Guillermo**

- ♦ Degree in Nursing from the Complutense University of Madrid (UCM).
- ♦ Master's Degree in Research Methodology in Health Care from the UCM.
- ♦ Expert in Nurse Prescription by the Distance University of Madrid (UDIMA).
- ♦ 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.

**D. Nieves Sedano, Marcos**

- ♦ Degree in Pharmacy Complutense University.
- ♦ Postgraduate Certificate in Statistics in Health Sciences. Autonomous University of Barcelona.
- ♦ Specialist in Hospital Pharmacy. 12 de Octubre University Hospital.
- ♦ Area Specialist (Onco-hematological Clinical Trials). Research Pharmacist. Intensive Care Medicine. (Research Pharmacist).

**Ms. Ochoa Parra, Nuria**

- ♦ Degree in Pharmacy from the Complutense University of Madrid.
- ♦ Master's Degree in Clinical Trials from the University of Seville.
- ♦ D. 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.

**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.
- ♦ Ms. Martín Torres, M<sup>a</sup> Paz
- ♦ Degree in Medicine and Surgery from the Complutense University of Madrid.
- ♦ Qualified as a General Primary Care Physician by the Ministry of Health and Consumer Affairs.

**Ms. Pérez Indigua, Carla**

- ♦ Degree in Nursing. Complutense University of Madrid.
- ♦ Master's Degree in Research Methodology in Health Care from the UCM.
- ♦ D. candidate in Health Care. Complutense University of Madrid.
- ♦ Research Nurse in the Clinical Pharmacology Service of the San Carlos Clinical Hospital.
- ♦ Professor of the subject "Ethics of research with human beings" in the Professional Master's Degree of Applied Ethics of the Faculty of Philosophy of the UCM.

**Dr. Rodríguez Jiménez, Roberto**

- ♦ Degree in Medicine and Surgery.
- ♦ Degree in Psychology.
- ♦ Master's Degree in Psychotherapy.
- ♦ PhD in Psychiatry
- ♦ Alcoholism Specialist
- ♦ Director of the Inpatient Unit, Day Hospital, Emergency Room, Electroconvulsive Therapy Program and Psychosis Program.





**Ms. Santacreu Guerrero, Mireia**

- ◆ Degree in Nursing from the European University of Madrid.
- ◆ Master's Degree in Nursing Management from the same University.
- ◆ Nurse Clinical Trials Coordinator at the HIV Unit of the 12 de Octubre University Hospital, Madrid.

**Dr. Sánchez Ostos Manuel**

- ◆ Master's Degree in Clinical Trial Monitoring and Pharmaceutical Development. University of Nebrija (Madrid)
- ◆ Professional Master's Degree in Biotechnology. University of Córdoba
- ◆ Master's Degree in Teacher Training. University of Córdoba
- ◆ Degree in Biology. University of Córdoba

**Dr Valtueña Murillo, Andrea**

- ◆ Pharmaceutical Industry. Community Pharmacy. Hospital Pharmacy
- ◆ Professional 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.

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.





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*This Postgraduate Diploma contains the most complete and up-to-date scientific program on the market"*

## Module 1. Research and Development of Medicines

- 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. Biostatistics

- 2.1. Study Design
  - 2.1.1. Research Question
  - 2.1.2. Population to be Analyzed
  - 2.1.3. Classification
    - 2.1.3.1. Comparison between Groups
    - 2.1.3.2. Maintenance of the Described Conditions
    - 2.1.3.3. Assignment to Treatment Group
    - 2.1.3.4. Blinding Degree
    - 2.1.3.5. Modality of Intervention
    - 2.1.3.6. Centers Involved



- 2.2. Types of Randomized Clinical Trials Validity and Biases
  - 2.2.1. Types of Clinical Trials
    - 2.2.1.1. Superiority Study
    - 2.2.1.2. Equivalence or Bioequivalence Study
    - 2.2.1.3. Non-Inferiority Study
  - 2.2.2. Analysis and Validity of Results
    - 2.2.2.1. Internal Validity
    - 2.2.2.2. External Validity
  - 2.2.3. Biases
    - 2.2.3.1. Selection
    - 2.2.3.2. Measurement
    - 2.2.3.3. Confusion
- 2.3. Sample Size Protocol Deviations
  - 2.3.1. Parameters to be Used
  - 2.3.2. Protocol Justification
  - 2.3.3. Protocol Deviations
- 2.4. Methodology
  - 2.4.1. Missing Data Handling
  - 2.4.2. Statistical Methods
    - 2.4.2.1. Description of Data
    - 2.4.2.2. Survival
    - 2.4.2.3. Logistic Regression
    - 2.4.2.4. Mixed Models
    - 2.4.2.5. Sensitivity Analysis
    - 2.4.2.6. Multiplicity Analysis
- 2.5. When Does the Statistician Become Part of the Project
  - 2.5.1. Statistician Role
  - 2.5.2. Points of the Protocol to be Reviewed and Described by the Statistician
    - 2.5.2.1. Study Design
    - 2.5.2.2. The Primary and Secondary Objectives of the Study
    - 2.5.2.3. Sample Size Calculation
    - 2.5.2.4. Variables:
    - 2.5.2.5. Statistical Justification
    - 2.5.2.6. Material and Methods used to Study the Objectives of the Study

- 2.6. Design of the CRF (Case Report Form)
  - 2.6.1. Data Collection: Dictionary of Variables
  - 2.6.2. Variables and Data Entry
  - 2.6.3. Database Security, Testing and Debugging
- 2.7. Statistical Analysis Plan
  - 2.7.1. What is a Statistical Analysis Plan?
  - 2.7.2. When to Perform the Statistical Analysis Plan
  - 2.7.3. Statistical Analysis Plan Parts
- 2.8. Intermediate Analysis
  - 2.8.1. Reasons for an Early Stopping of a Clinical Trial
  - 2.8.2. Implications of Early Termination of a Clinical Trial
  - 2.8.3. Statistical Designs
- 2.9. Final Analysis
  - 2.9.1. Final Report Criteria
  - 2.9.2. Plan Deviations
  - 2.9.3. Guidelines for the Elaboration of the Final Report of a Clinical Trial
- 2.10. Statistical Review of a Protocol
  - 2.10.1. *Checklist*
  - 2.10.2. Frequent Errors in the Review of a Protocol

### Module 3. Bioethics and Regulations

- 3.1. Basic Ethical Principles and Most Relevant Ethical Norms
  - 3.1.1. Aims of Biomedical Science
  - 3.1.2. Rights and Freedoms of Researchers
  - 3.1.3. Limits to the Right of Research
  - 3.1.4. Ethical Principles of Clinical Research
  - 3.1.5. Conclusions
- 3.2. Ethical Assessment of Clinical Research on Drugs and Medical Devices
  - 3.2.1. Introduction
  - 3.2.2. Areas of Bioethics

- 3.2.1.1. General aspects
    - 3.2.1.2. Research Ethics
  - 3.2.3. Justification of Bioethics
    - 3.2.3.1. Clinical Indeterminacy
    - 3.2.3.2. Relevance of Scientific Objectives
    - 3.2.3.3. Preclinical Data
  - 3.2.4. Ethical Conditions of Clinical Trial Designs
  - 3.2.5. Drug Research Ethics Committees
    - 3.2.5.1. Definition
    - 3.2.5.2. Functions
    - 3.2.5.3. Composition
    - 3.2.5.4. Conclusions
- 3.3. Subject Selection in Clinical Trials
  - 3.3.1. Criteria
  - 3.3.2. Special Patients and Vulnerability
  - 3.3.3. Vulnerability Assessment
    - 3.3.3.1. Age
    - 3.3.3.2. Severity of Disease
    - 3.3.3.3. Other Types of Vulnerability
    - 3.3.3.4. Vulnerability Protection
  - 3.3.4. Conclusions
- 3.4. Risk-Benefit Balance in Clinical Trials
  - 3.4.1. Potential Benefits
  - 3.4.2. Potential Risks
  - 3.4.3. Minimizing Risks
  - 3.4.4. Risk Level Assessment
  - 3.4.5. Final Assessment of the Risk-Benefit Balance
  - 3.4.6. Conclusions
- 3.5. Protection, Informed Consent and Participant Information Form
  - 3.5.1. Participant Information Form (PIF)
    - 3.5.1.1. Type of Information Provided
    - 3.5.1.2. Information Processing
  - 3.5.2. Informed Consent
    - 3.5.2.1. Concepts
    - 3.5.2.2. Obtaining Procedure
    - 3.5.2.3. Clinical Trials with Minors
    - 3.5.2.4. Clinical Trials with Patients with Modified Capacity to Give Consent
    - 3.5.2.5. Clinical Trials in Emergency Situations
    - 3.5.2.6. Clinical Trials in Pregnant or Breastfeeding Women
    - 3.5.2.7. Clinical trials on the Disabled
    - 3.5.2.8. Informed Consent for Genetic Studies
  - 3.5.3. Insurance and Financial Compensation
    - 3.5.3.1. Safety
    - 3.5.3.2. Compensation
    - 3.5.3.3. Compensation
  - 3.5.4. Confidentiality
  - 3.5.5. Violations
  - 3.5.6. Continuation of Treatment After the Trial
  - 3.5.7. Conclusions
- 3.6. Good Clinical Practices in Clinical Trials
  - 3.6.1. History
  - 3.6.2. Legal and Ethical Framework
  - 3.6.3. Guideline for Good Clinical Practice (GCP)
    - 3.6.3.1. Basic Principles
    - 3.6.3.2. Drug Research Ethics Committee (CEIM)
    - 3.6.3.3. Researcher
    - 3.6.3.4. Promoter
    - 3.6.3.5. Protocol
    - 3.6.3.6. Investigators Brochure (IB)
    - 3.6.3.7. Promoters Manual
    - 3.6.3.8. Essential Documents
  - 3.6.4. Conclusions
- 3.7. Legislation on Clinical Trials with Drugs and Healthcare Products
  - 3.7.1. Introduction
  - 3.7.2. EXCLUSIVO DE ESPAÑA
    - 3.7.2.1. Law 26/2006
    - 3.7.2.2. EXCLUSIVO DE ESPAÑA
    - 3.7.2.3. Law 41/2002



- 3.7.3. Drugs Used in Clinical Trials
  - 3.7.3.1. Manufacturing and Importation
  - 3.7.3.2. Labelling
  - 3.7.3.3. Acquisition
  - 3.7.3.4. Unused Drug
- 3.7.4. European Legislation
- 3.7.5. FDA, EMA and AEMPS
- 3.7.6. Communication
- 3.7.7. Conclusions
- 3.8. Legislation on Clinical Trials with Healthcare Products
  - 3.8.1. Introduction
  - 3.8.2. EXCLUSIVO DE ESPAÑA
  - 3.8.3. Clinical Research with Medical Devices
  - 3.8.4. European Legislation
  - 3.8.5. Conclusions
- 3.9. Authorization and Registration Procedures for Drugs and Medical Devices
  - 3.9.1. Introduction
  - 3.9.2. Definitions
  - 3.9.3. Drugs Authorization
  - 3.9.4. Drugs Dispensing
  - 3.9.5. Public Funding
  - 3.9.6. Conclusions
- 3.10. Legislation on Post-Authorization Studies
  - 3.10.1. What are Post-Authorization Trials?
  - 3.10.2. Studies Justification
  - 3.10.3. Classification
    - 3.10.3.1. Security/safety
    - 3.10.3.2. Drug Utilization Studies (DUS)
    - 3.10.3.3. Pharmacoeconomic Studies
  - 3.10.4. Guidelines
  - 3.10.5. Administrative Procedures
  - 3.10.6. Conclusions

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.





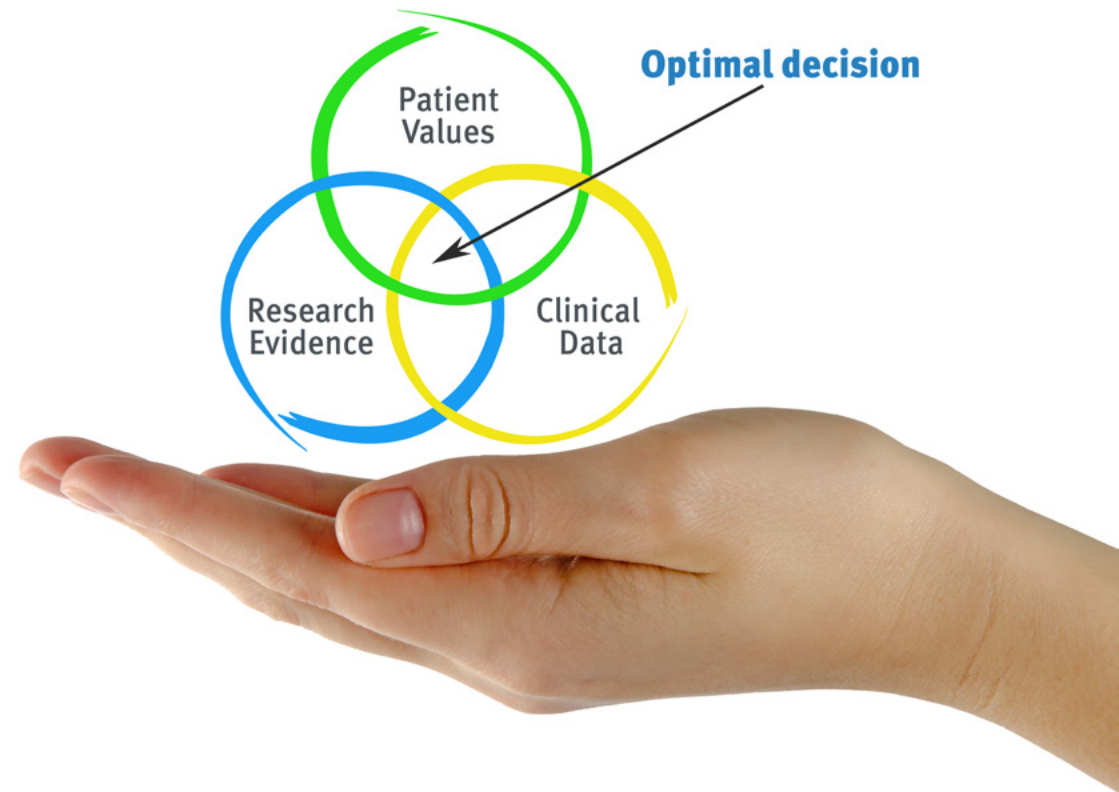


*Discover Relearning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"*

## At TECH we use the Case Method

What should a professional do in a given situation? Throughout the program, students will be confronted with multiple simulated clinical cases based on real patients, in which they will have to investigate, establish hypotheses and ultimately, resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Pharmacists learn better, more quickly 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. Gervas, 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, attempting to recreate the actual conditions in a pharmacist'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. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their 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.

Our 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, which represent a real revolution with respect to simply studying and analyzing cases.

*Pharmacists 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, more than 115,000 pharmacists have been trained with unprecedented success in all clinical specialties, regardless of the surgical load. This pedagogical methodology is developed in a highly demanding environment, with a university student body with a high socioeconomic profile and an average age of 43.5 years.

*Relearning will allow you to learn with less effort and better performance, involving you more in your 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 created specifically for the course by specialist pharmacists who will be teaching the course, so that the didactic development is highly specific and accurate.

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.



### Video Techniques and Procedures

TECH introduces students to the latest techniques, to the latest educational advances, to the forefront of current pharmaceutical care procedures. All of this, first hand, and explained and detailed with precision to contribute to assimilation and a better 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 unique multimedia content presentation training system 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, we will present you with real case developments in which the expert will guide you through 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 Research and Development of Medicines guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Diploma issued by TECH Global University.





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*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 Diploma in Research and Development of Medicines** 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 Diploma in Research and Development of Medicines**

Modality: **online**

Duration: **6 months**

Accreditation: **18 ECTS**



\*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.

future

health confidence people

education information tutors

guarantee accreditation teaching

institutions technology learning

community commitment

personalized service innovation

knowledge present quality

online tra

development languages

virtual classroom

**tech** global  
university

## Postgraduate Diploma Research and Development of Medicines

- » Modality: online
- » Duration: 6 months
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- » Credits: 18 ECTS
- » Schedule: at your own pace
- » Exams: online

# Postgraduate Diploma Research and Development of Medicines

