Postgraduate Certificate
Drug Research and Development

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Postgraduate Certificate
Drug Research and Development

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

Website: **www.techtitute.com/pk/pharmacy/postgraduate-certificate/research-development-medicines**

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01

Introduction

The emergence of new diseases and the need to find effective treatments for pathologies for which there is still no cure, invites us to make more and more efforts in the field of research, a sector that can bring great benefits to society, but for which constant investment is needed. With this instructional program, TECH wants to specialize pharmacists in drug development, offering them a new methodology and a completely up-to-date program.

The current importance of pharmacological research makes this Postgraduate Certificate an essential education for pharmacists. Don't think twice and specialize with us"

In the field of drug research, the pharmacist must have a broad knowledge of all aspects related to drug development, but they must also have sufficient knowledge of statistics to be able to conduct clinical trials as accurately as possible.

The importance of statistical knowledge is due to the fact that it is the most appropriate way to reach reasonable and accurate conclusions from the information collected, and to probe decisions when certainties are scarce. Therefore, education in this field is essential for pharmacists specializing in the research sector.

In addition, a very important part of the Research and Development of Medicines process is to know how to communicate the new discoveries, which will allow further research in this field and promote its use in a generalized way, achieving a subsequent benefit for patients. Therefore, this program brings together all these sections, which will allow the professional to obtain a global but accurate vision of the process of Research and Development of Medicines.

As a perfect complement to this very complete program, TECH offers students a completely new educational methodology in a 100% online format, one of the main advantages of studying at this university. In this way, our students only need to have a computer or mobile device with an internet connection, and can continue their education from anywhere in the world, without limits of borders or schedules, and combining their education with the rest of their daily obligations.

This **Postgraduate Certificate in Research and Development of Medicines** contains the most complete and up-to-date educational 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 work
- Content that is accessible from any fixed or portable device with an internet connection

Train with us in Research and Development of Medicines and specialize until you achieve excellence in this field"

This Postgraduate Certificate 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 Technological University"

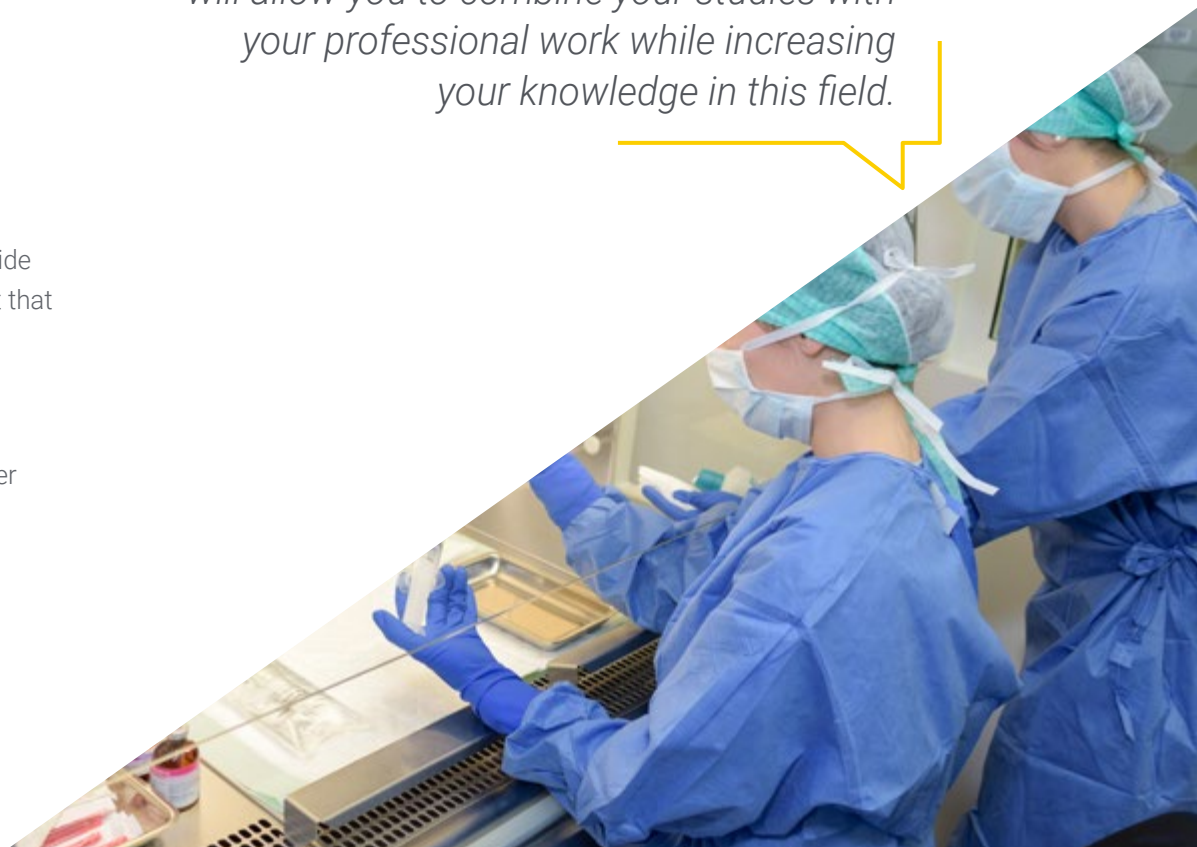
Do not hesitate to take this program with us. You will find the best teaching material with virtual lessons.

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

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.

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



02

Objectives

The Postgraduate Certificate in Research and Development of Medicines is designed to facilitate the performance of the research professional with the latest advances in the sector.

Thanks to this Postgraduate Certificate you will be able to specialize in Research and Development of Medicines 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
- Develop knowledge that provides a basis or opportunity for originality 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

Specific Objectives

- 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 medication
- 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
- 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
- Acquire an ethical and social commitment

03

Course Management

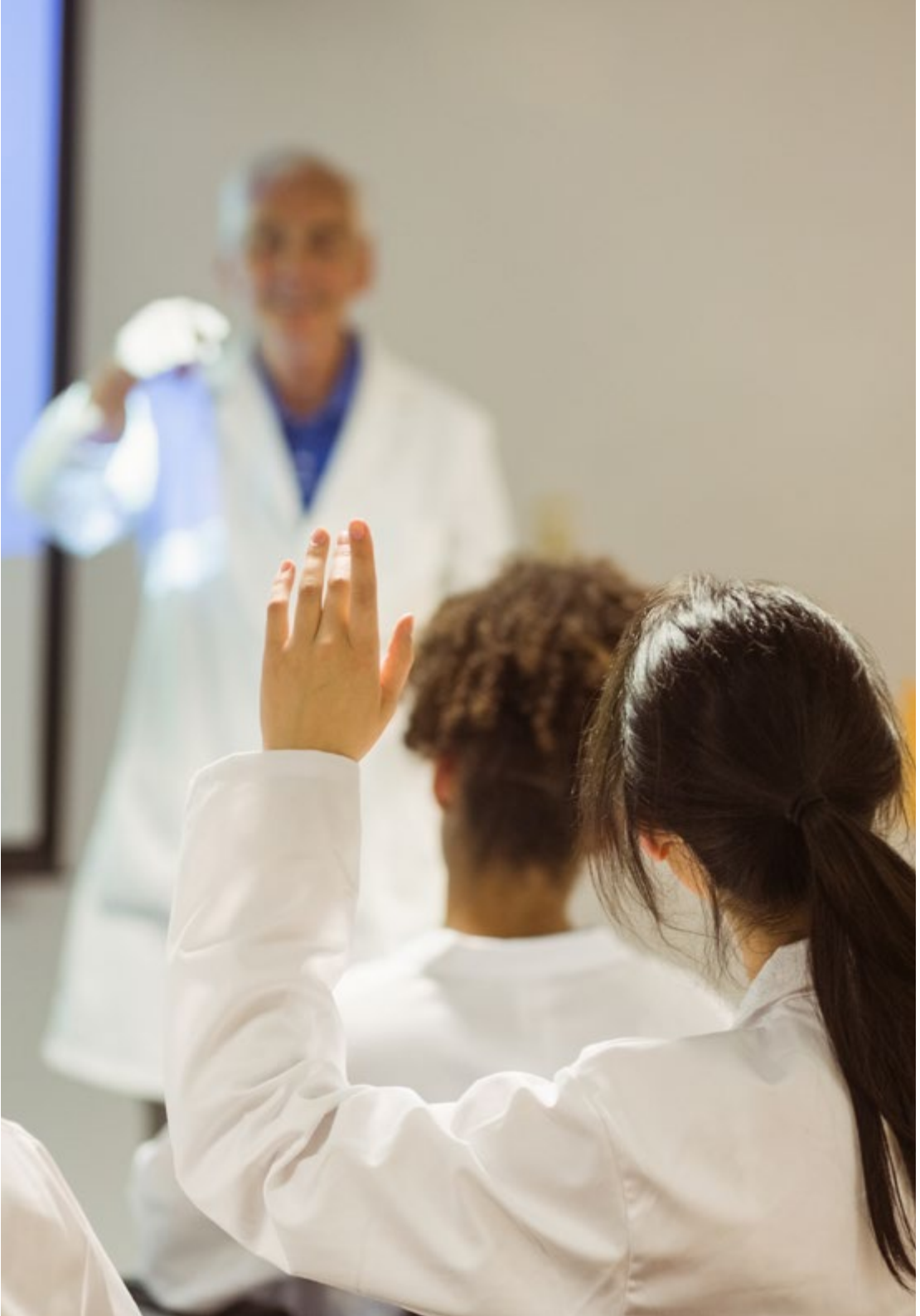
The program's teaching staff includes leading experts in research and health, who contribute their work experience to this education. In addition, other renowned experts participate in its design and development, completing the program in an interdisciplinary manner.

Leading experts in Research and Development of Medicines have come together to show you all their expertise 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

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

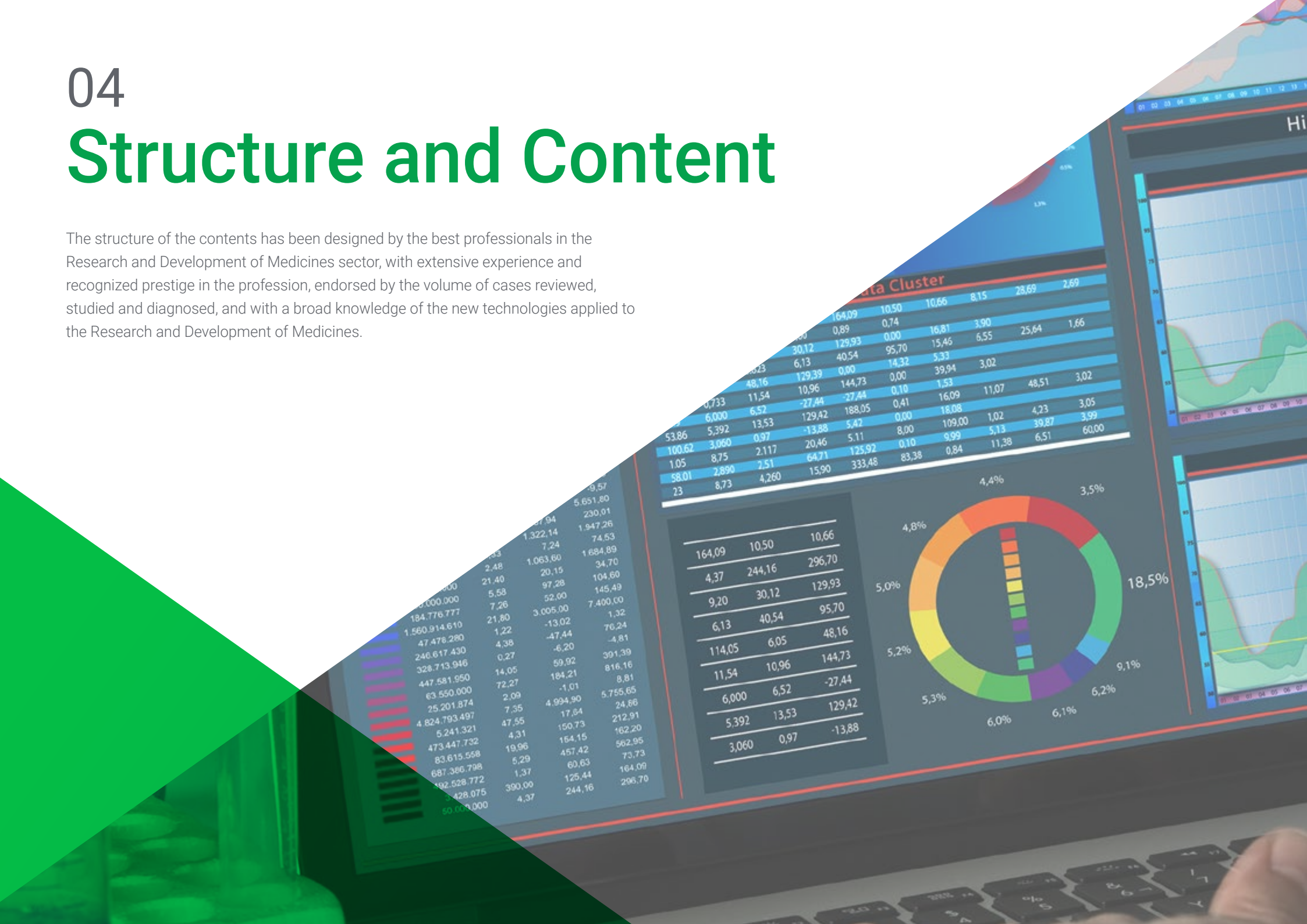
Ms. Martín-Arriscado Arroba, Cristina

- 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

04

Structure and Content

The structure of the contents has been designed by the best professionals in the Research and Development of Medicines sector, with extensive experience and recognized prestige in the profession, endorsed by the volume of cases reviewed, studied and diagnosed, and with a broad knowledge of the new technologies applied to the Research and Development of Medicines.



This Postgraduate Certificate in Research and Development of Medicines 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. 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

This will provide key training o advance your career"

05

Methodology

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

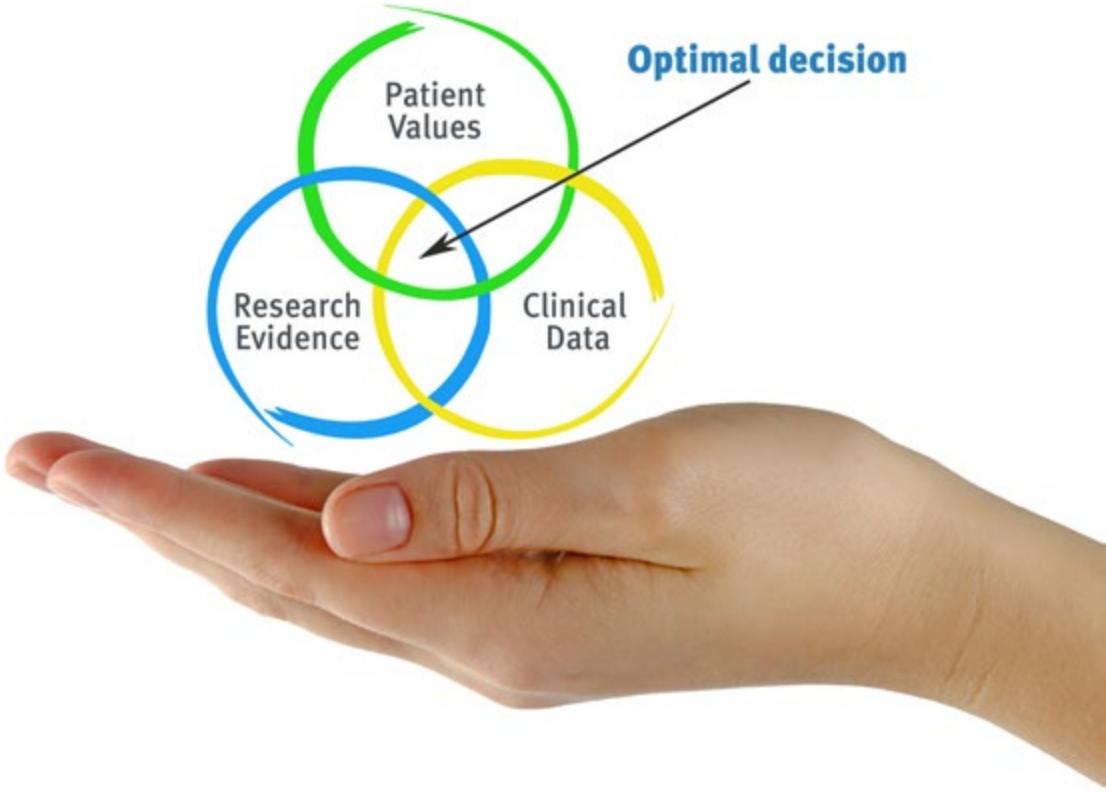
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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 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. 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, attempting to recreate the actual conditions in a pharmacist'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:

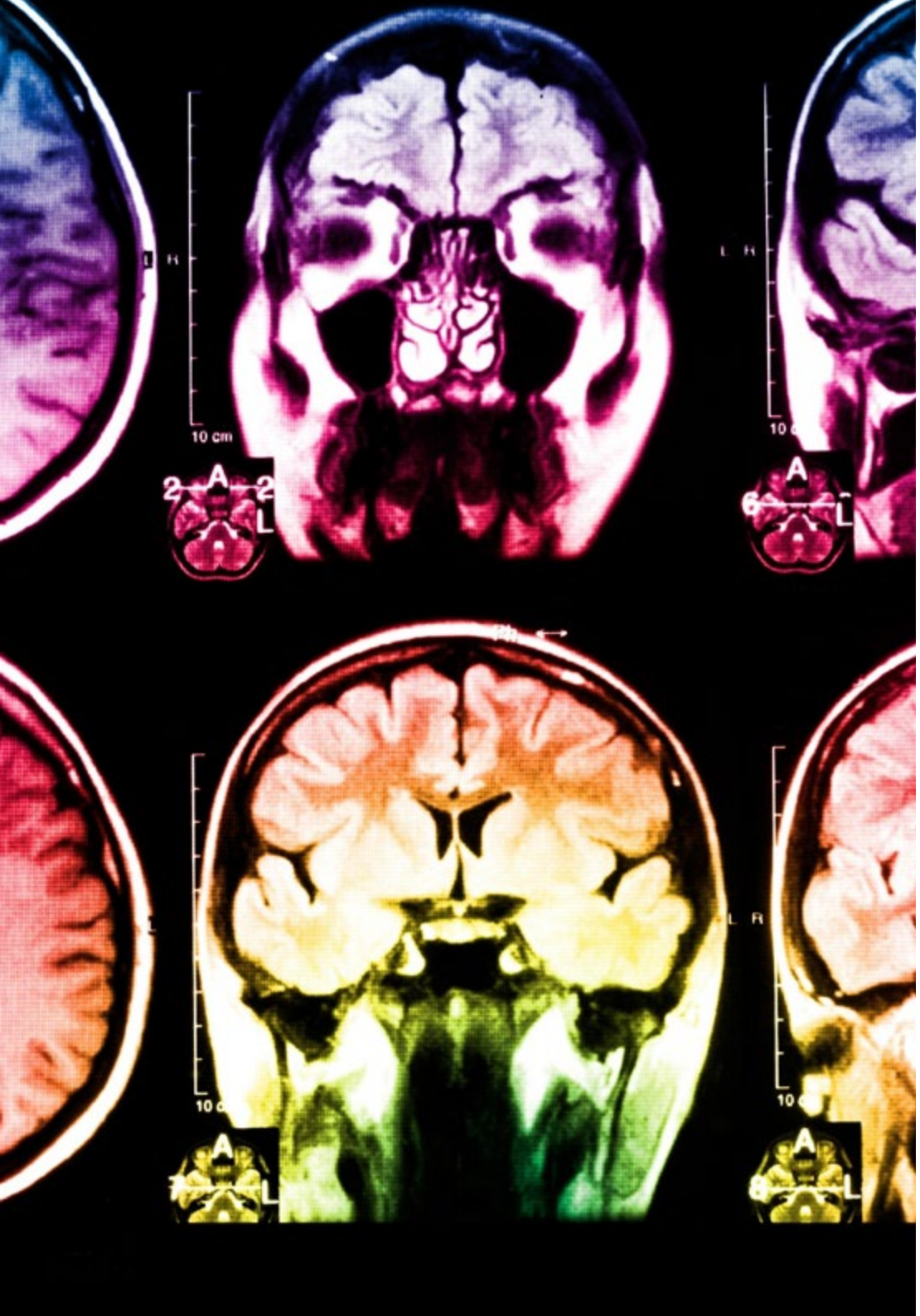
1. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts 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.

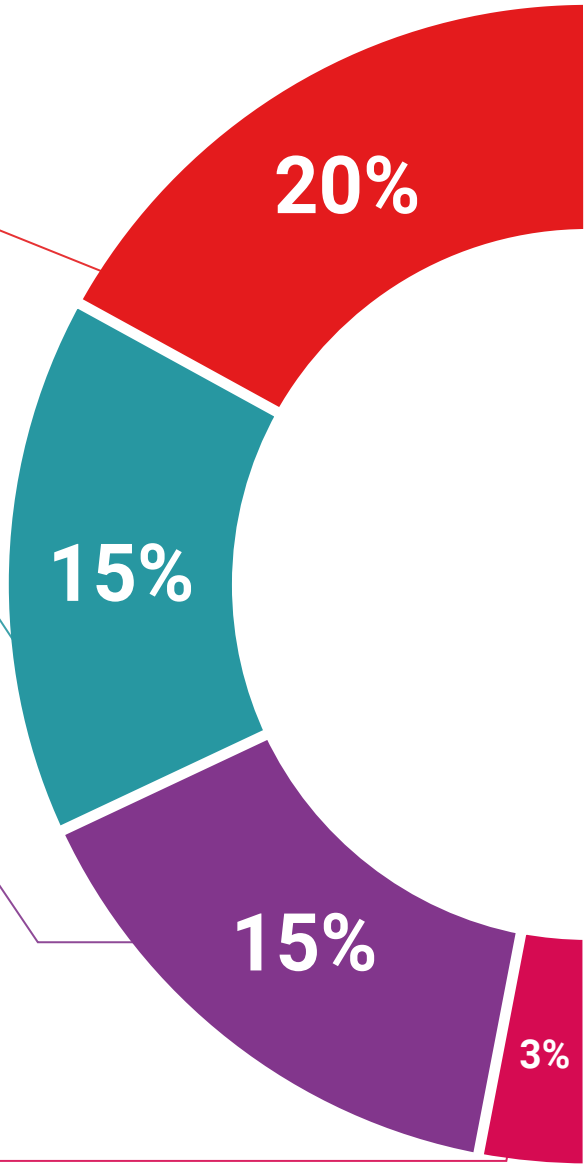
Interactive Summaries

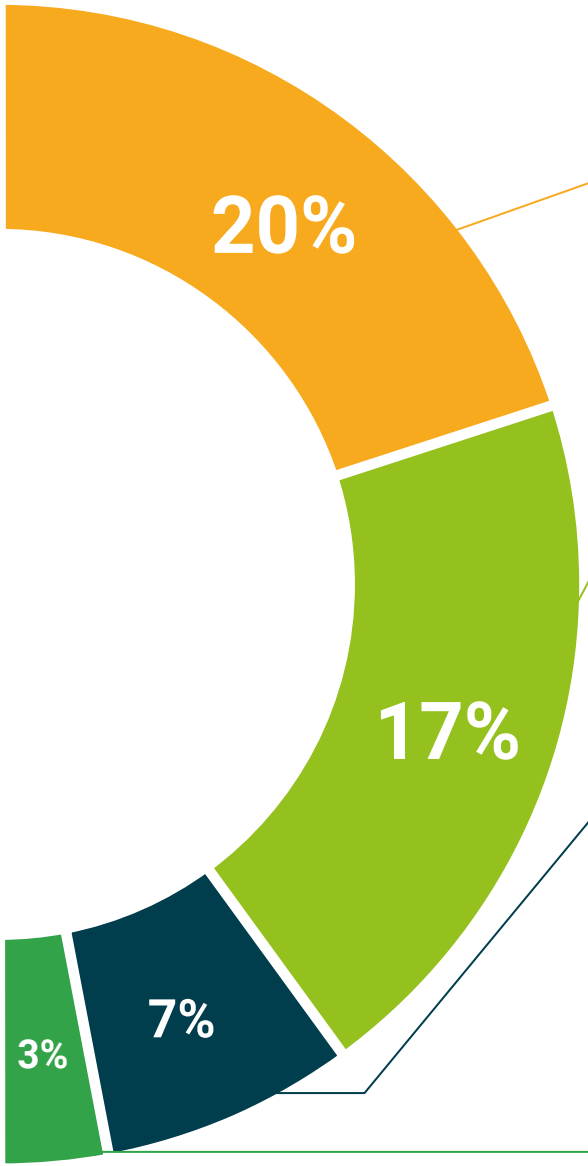
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Certificate in Research and Development of Medicines guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate 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 Certificate in Research and Development of Medicines** 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** diploma issued by **TECH Technological University** via tracked delivery*.

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

Title: **Postgraduate Certificate in Research and Development of Medicines**

Official Nº of Hours: **300 h.**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Awards the following

CERTIFICATE

to

Mr./Ms. _____, with identification number _____.

For having passed and accredited the following program

POSTGRADUATE CERTIFICATE

in

Research and Development of Medicines

This is a qualification awarded by this University, equivalent to 300 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH is a Private Institution of Higher Education recognized by the Ministry of Public Education as of June 28, 2018.

June 17, 2020

Tere Guevara Navarro
Dean

This qualification must always be accompanied by the university degree issued by the competent authority to practice professionally in each country.

Unique TECH Code: AFWORD23S techtitute.com/certificates

*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.

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Drug Research and Development

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