Postgraduate Diploma
Drug Research and Development in Nursing

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Postgraduate Diploma
Drug Research and Development in Nursing

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

Website: **www.techtitute.com/us/nursing/postgraduate-diploma/postgraduate-diploma-drug-research-development-nursing**

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01

Introduction

Investing in pharmacological research is essential for finding new drugs to improve the health and quality of life of patients. However, for this, it is also essential to have professionals prepared to carry out such research. Specifically, this program aimed at nurses aims to prepare them for drug research and development.

TECH offers this program for nurses who wish to specialize in the field of Drug Research and Development"

This Postgraduate Diploma in Drug Research and Development is designed to specialize nurses with a vocation in pharmacological research, a fundamental facet in finding new treatments for the fight against diseases for which a cure has not yet been found.

Thanks to this Postgraduate Diploma, students will delve into the study of preclinical drug research, as well as statistics, which is essential to reach reasonable and accurate conclusions. However, in any research, it is also essential to have a broad knowledge of the legislation in force in order to avoid regulatory or ethical errors.

In short, after completing this Postgraduate Diploma, the student will be able to comply with ethical standards in Clinical Trials, not only compliance with legislation to ensure the protection and enforcement of the rights of participants, but also in areas such as methodology, to ensure compliance with the standards of validity and reliability for the data obtained and the correct design of Clinical Trials.

In addition, this program has the advantage of being offered in a 100% online format, so the students 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 Drug Research and Development in Nursing** contains the most complete and up-to-date scientific program on the market. The most important features include:

- Practical cases presented by experts in Drug Research and Development
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- News on Drug Research and Development
- Practical exercises where the self-assessment process can be carried out to improve learning
- Its special emphasis on innovative methodologies in Drug Research and Development
- 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 Drug Research and Development that will enable you to achieve excellence in this field"

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 Drug Research and Development, you will obtain a qualification endorsed by the largest Digital University in the world: TECH"

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

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

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 learning programmed to study 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 a novel interactive video system developed by renowned and experienced experts in the field of Drug Research and Development.

02

Objectives

The program in Drug Research and Development in Nursing is oriented to facilitate the performance of the research professional with the latest advances in the sector.

Thanks to this Postgraduate Diploma, you will be able to learn about Drug Research and Development and 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 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

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
- Acquire an ethical and social commitment

Module 3. Bioethics and Regulations

- 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

An intensive course that will allow you to become an expert in Drug Research and Development in Nursing in a short period of time and with the utmost flexibility"

03

Course Management

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

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

- Military pharmacist at HMC Gómez Ulla
- 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

Professors

Ms. Valtueña Murillo, Andrea

- Technician in Quality, Regulation and Pharmacovigilance in Cantabria Labs
- Master in Pharmaceutical and Parapharmaceutical Industry in CESIF
- Degree in Pharmacy at Complutense University of Madrid

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

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

A path to achieve education and professional growth that will propel you towards a greater level of competitiveness in the employment market"

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

Module 1. Drug Research and Development in Nursing

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 Interventions

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 Analyze
- 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. Degree of Masking
  - 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 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. CRD Design
- 2.6.1. Information Gathering Variables Dictionary
- 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 a 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 Evaluation 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 with 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. Indemnification
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 Medical Devices
3.7.1. Introduction
3.7.2. EXCLUSIVO DE ESPAÑA
3.7.2.1. Law 26/2006
3.7.2.2. RD 1090/2015
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
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.**

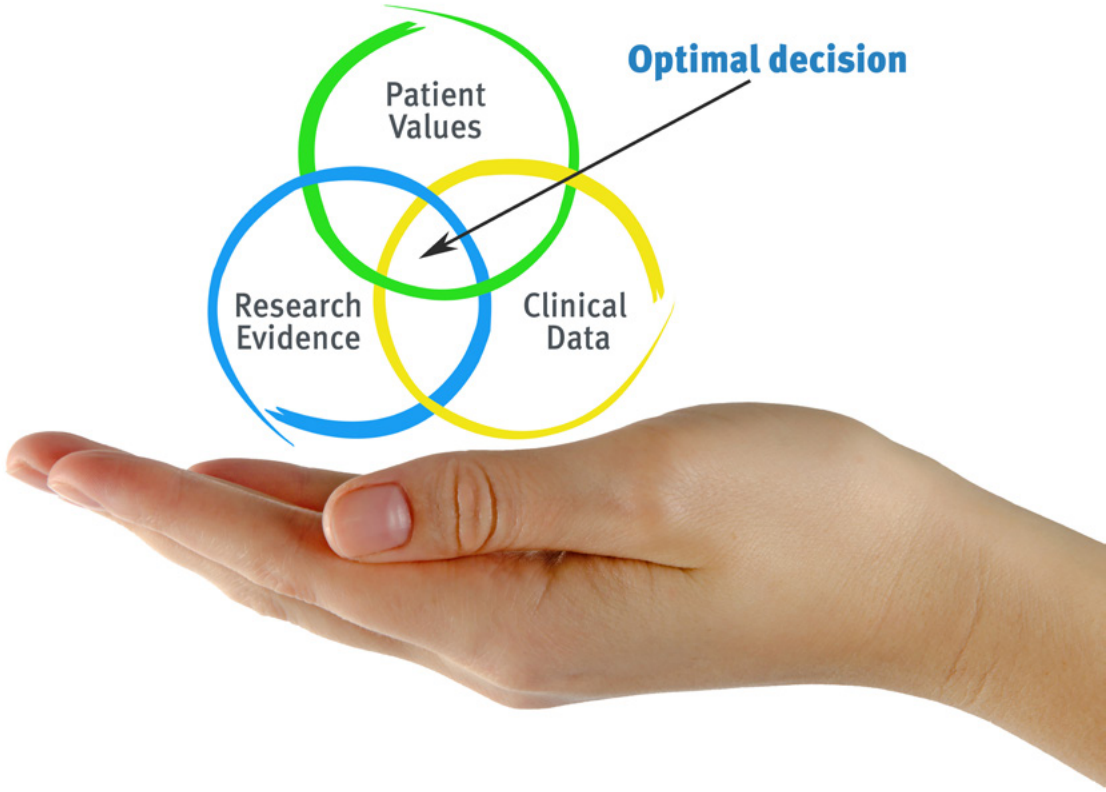
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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 Nursing School we use the Case Method

In a given situation, what should a professional do? Throughout the program, students will face multiple simulated clinical cases, based on real patients, in which they will have to do research, establish hypotheses, and ultimately resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Nurses learn better, faster, and more sustainably over time.

With TECH, nurses can experience a learning methodology that is shaking the foundations of traditional universities around the world.



According to Dr. Gérvas, the clinical case is the annotated presentation of a patient, or group of patients, which becomes a "case", an example or model that illustrates some peculiar clinical component, either because of its teaching power or because of its uniqueness or rarity. It is essential that the case is based on current professional life, in an attempt to recreate the real conditions in professional nursing practice.

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

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

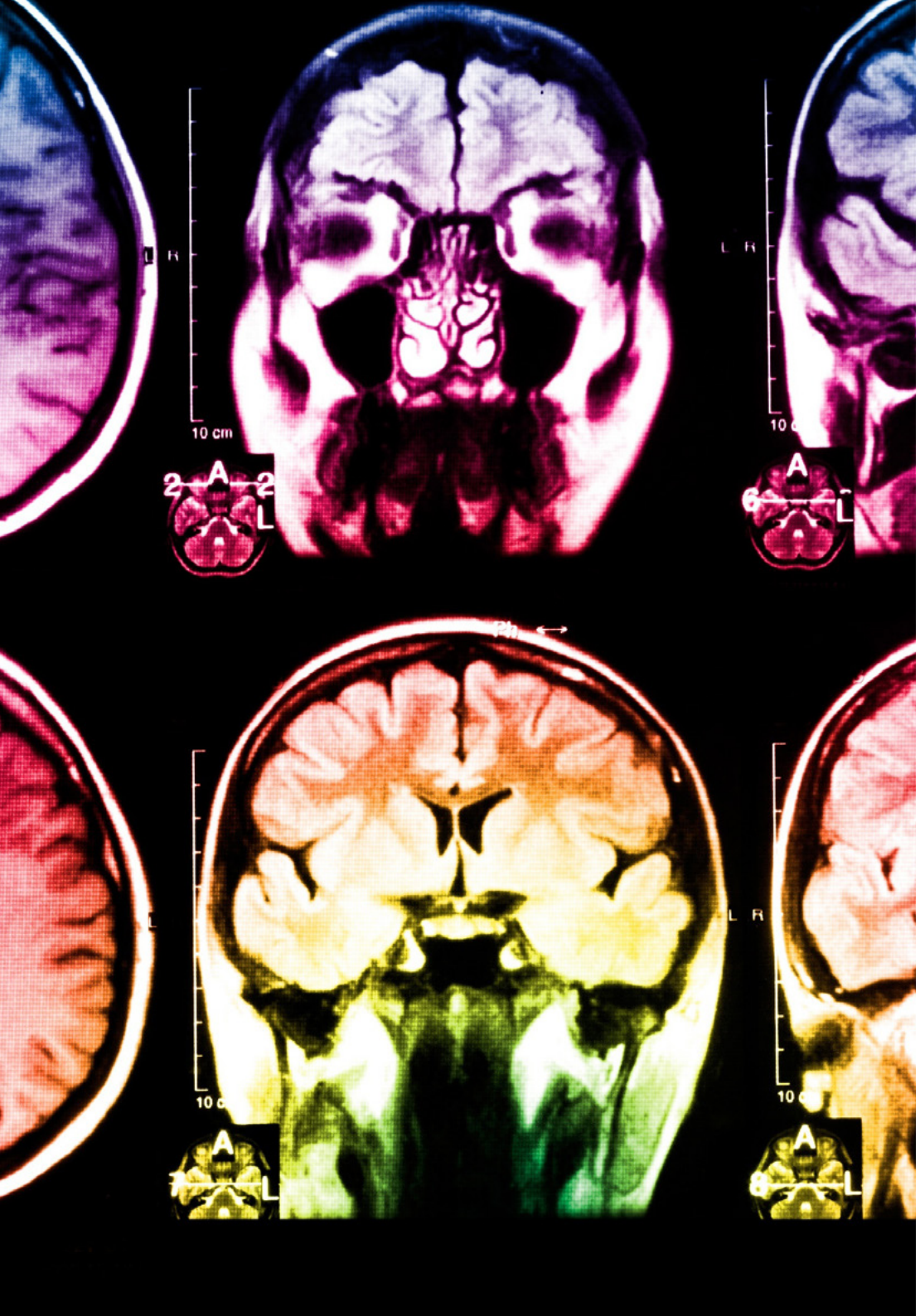
1. Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into the hospital setting or primary care.
3. Ideas and concepts are understood more efficiently, given that the example situations are based on real-life.
4. Students like to feel that the effort they put into their studies is worthwhile. This then translates into a greater interest in learning and more time dedicated to working on the course.

Relearning Methodology

At TECH we enhance the case method with the best 100% online teaching methodology available: Relearning.

This university is the first in the world to combine case studies with a 100% online learning system based on repetition combining a minimum of 8 different elements in each lesson, which is a real revolution compared to the simple study and analysis of cases.

The nurse will learn through real cases and by solving complex situations in simulated learning environments. These simulations are developed using state-of-the-art software to facilitate immersive learning.



At the forefront of world teaching, the Relearning method has managed to improve the overall satisfaction levels of professionals who complete their studies, with respect to the quality indicators of the best online university (Columbia University).

With this methodology we have trained more than 175,000 nurses with unprecedented success in all specialities regardless of practical workload. Our pedagogical methodology is developed in a highly competitive environment, with a university student body with a strong socioeconomic profile and an average age of 43.5 years old.

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

In our program, learning is not a linear process, but rather a spiral (learn, unlearn, forget, and re-learn). Therefore, we combine each of these elements concentrically.

The overall score obtained by TECH's learning system is 8.01, according to the highest international standards.

This program offers the best educational material, prepared with professionals in mind:

Study Material

All teaching material is produced by the specialists who teach the course, specifically for the course, so that the teaching content is really specific and precise.

These contents are then applied to the audiovisual format, to create the TECH online working method. All this, with the latest techniques that offer high quality pieces in each and every one of the materials that are made available to the student.

Nursing Techniques and Procedures on Video

We introduce you to the latest techniques, to the latest educational advances, to the forefront of current medical techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch them as many times as you want.

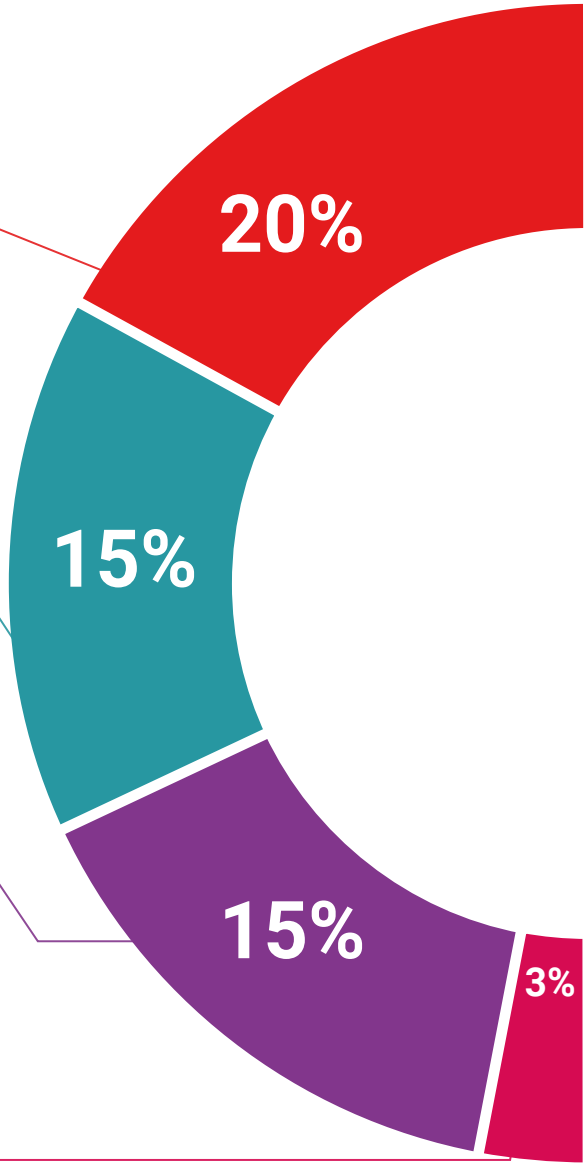
Interactive Summaries

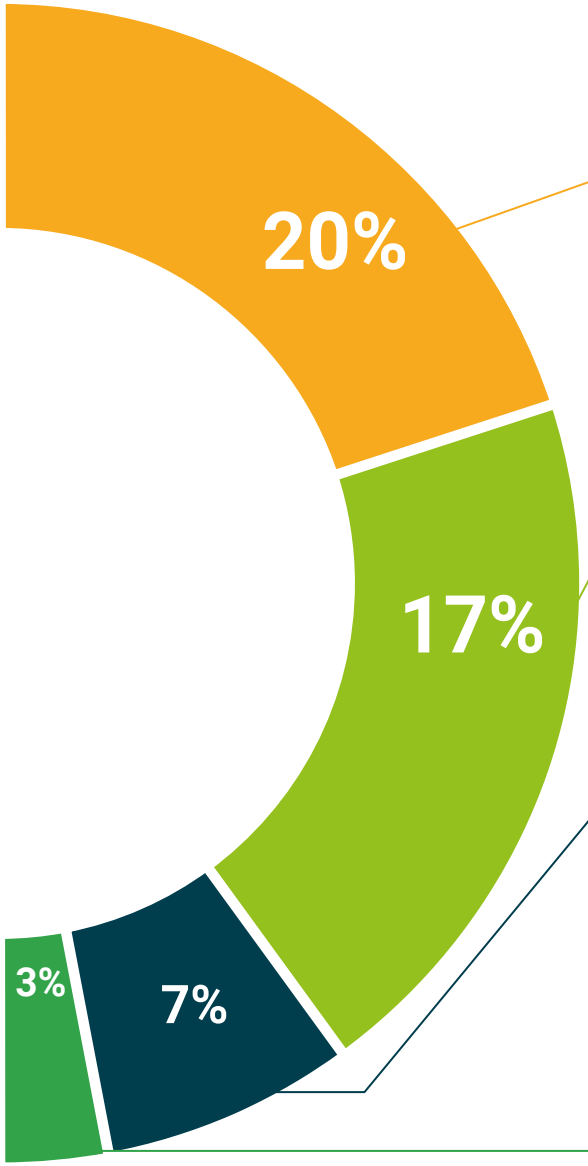
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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

Additional Reading

Recent articles, consensus documents and international guidelines, among others. In TECH's virtual library, students will have access to everything they need to complete their course.





Expert-Led Case Studies and Case Analysis

Effective learning ought to be contextual. Therefore, TECH presents real cases in which the expert will guide students, focusing on and solving the different situations: a clear and direct way to achieve the highest degree of understanding.

Testing & Retesting

We periodically evaluate and re-evaluate students' knowledge throughout the program, through assessment and self-assessment activities and exercises, so that they can see how they are achieving their goals.

Classes

There is scientific evidence suggesting that observing third-party experts can be useful.

Learning from an Expert strengthens knowledge and memory, and generates confidence in future difficult decisions.

Quick Action Guides

TECH offers the most relevant contents of the course in the form of worksheets or quick action guides. A synthetic, practical, and effective way to help students progress in their learning.

06

Certificate

The Postgraduate Diploma in Drug Research and Development in Nursing 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 private qualification will allow you to obtain a **Postgraduate Diploma in Drug Research and Development in Nursing** endorsed by **TECH Global University**, the world's largest online university.

TECH Global University is an official European University publicly recognized by the Government of Andorra (***official bulletin***). Andorra is part of the European Higher Education Area (EHEA) since 2003. The EHEA is an initiative promoted by the European Union that aims to organize the international training framework and harmonize the higher education systems of the member countries of this space. The project promotes common values, the implementation of collaborative tools and strengthening its quality assurance mechanisms to enhance collaboration and mobility among students, researchers and academics.

This **TECH Global University** private qualification is a European program of continuing education and professional updating that guarantees the acquisition of competencies in its area of knowledge, providing a high curricular value to the student who completes the program.

Title: **Postgraduate Diploma in Drug Research and Development in Nursing**

Modality: **online**

Duration: **6 months**

Accreditation: **18 ECTS**


tech global university

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

Postgraduate Diploma in Drug Research and Development in Nursing

This is a private qualification of 540 hours of duration equivalent to 18 ECTS, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH Global University is a university officially recognized by the Government of Andorra on the 31st of January of 2024, which belongs to the European Higher Education Area (EHEA).

In Andorra la Vella, on the 28th of February of 2024

Dr. Pedro Navarro Illana
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 diploma issued with an apostille, TECH Global University will make the necessary arrangements to obtain it, at an additional cost.

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