Postgraduate Diploma
Clinical Trials Monitoring

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Postgraduate Diploma
Clinical Trials Monitoring

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

Website: www.techtitute.com/us/medicine/postgraduate-diploma/postgraduate-diploma-clinical-trials-monitoring

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01

Introduction

The monitoring of clinical trials is one of the most important facets of medical research, since the person responsible for this process must validate the results achieved, which is the basis for improving the quality of life of patients.

"The goal of health care is to achieve cures for diseases and to provide patients with a better quality of life. Investing in research is important, but so is having specialized professionals"

The Postgraduate Diploma in Clinical Trials Monitoring provides students with comprehensive training in the field of clinical research, a key element in the discovery of new drugs to improve the quality of life of patients. A key role in this process is played by the trial monitor, who is responsible for ensuring that the results obtained are reliable.

In this case, the main functions of the sponsor are analyzed, including the design of the protocol on the basis of which the entire clinical trial is developed, and the promoter's responsibility for the "verification of the adequate and effective monitoring of the clinical trial" is evaluated, in order to establish the close relationship between the sponsor and the monitor. As such, it specifies the profile of the monitor and the skills and abilities to ensure the proper functioning of the study within the research center, complying with Good Clinical Practice standards and protocol requirements.

On the other hand, the final part of the clinical trial and the SOPs (Standard Operating Procedures) that the CROs (Clinical Research Organizations) propose to the monitors will also be shown.

In short, a global vision of the monitoring process is presented, so that the healthcare professional will be able to acquire specialized knowledge that will serve as a guide for carrying out this work in a specialized center.

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

- The development of practical case studies presented by experts in Clinical Trials Monitoring
- 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 Monitoring
- Practical exercises where self-assessment can be used to improve learning
- Special emphasis on innovative methodologies in Clinical Trials Monitoring
- 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

This Postgraduate Diploma in Clinical Trials Monitoring will allow you to specialize until you achieve excellence in your profession"

This Postgraduate Diploma is the best investment you can make when selecting a refresher program to expand your existing knowledge of Clinical Trials Monitoring"

Do not hesitate to take this training 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.

The teaching staff includes professionals from the Health sector, who bring their experience to this training program, as well as renowned specialists from leading societies and prestigious universities.

The multimedia content, developed with the latest educational technology, will provide the professional with situated and contextual learning, i.e., a simulated environment that will provide immersive training programmed to train in real situations.

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

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Objectives

The Postgraduate Diploma in Clinical Trials Monitoring 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 Monitoring, 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 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. Clinical Trials (I)

- 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. Monitoring of Clinical Trials (I)

- 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. Monitoring of Clinical Trials (II)

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

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Course Management

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

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

Management

Dr. Gallego Lago, Vicente

- Doctoral studies with the qualification of Outstanding
- Honors Degree in Pharmacy from the Complutense University of Madrid
- Resident Internal Pharmacist Examination obtaining the No. 1 in this selective test
- Resident Internal Pharmacist of the Pharmacy Service of the "12 de Octubre Hospital". Madrid

Professors

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. 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, 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"

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

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

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

05

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

Module 1. Clinical Trials (I)

1.1. Clinical Trials. Fundamental Concepts I
- 1.1.1. Introduction
- 1.1.2. Definition of clinical trial (CT)
- 1.1.3. History of Clinical Trials
- 1.1.4. Clinical Research
- 1.1.5. Parties Involved in CTs
- 1.1.6. Conclusions

1.2. Clinical Trials. Fundamental Concepts II
- 1.2.1. Standards of Good Clinical Practice
- 1.2.2. Clinical Trial Protocol and Annexes
- 1.2.3. Pharmacoeconomic Assessment
- 1.2.4. Aspects that Could Be Improved in Clinical Trials

1.3. Clinical Trials Classification
- 1.3.1. Clinical Trials Purpose
- 1.3.2. Clinical Trials According to the Scope of Research
- 1.3.3. Clinical Trials Methodology
- 1.3.4. Treatment Groups
- 1.3.5. Clinical Trials Masking
- 1.3.6. Treatment Assignment

1.4. Phase I Clinical Trials
- 1.4.1. Introduction
- 1.4.2. Phase I Clinical Trials Characteristics
- 1.4.3. Phase I Clinical Trials Design
  - 1.4.3.1. Single Dose Trials
  - 1.4.3.2. Multiple Dose Trials
  - 1.4.3.3. Pharmacodynamic Studies
  - 1.4.3.4. Pharmacokinetic Studies
  - 1.4.3.5. Bioavailability and Bioequivalence Studies
- 1.4.4. Phase I Units
- 1.4.5. Conclusions

1.5. Non-commercial Research
- 1.5.1. Introduction
- 1.5.2. Non-commercial Research
- 1.5.3. Start-up of Non-commercial Clinical Trials
- 1.5.4. Difficulties of the Independent Promoter
- 1.5.5. Promotion of Independent Clinical Research
- 1.5.6. Application for Grants for Non-commercial Clinical Research
- 1.5.7. Bibliography

1.6. Equivalence and Non-Inferiority Cts (I)
- 1.6.1. Equivalence and Non-Inferiority Clinical Trials
  - 1.6.1.1. Introduction
  - 1.6.1.2. Justification
  - 1.6.1.3. Therapeutic Equivalence and Bioequivalence
  - 1.6.1.4. Concept of Therapeutic Equivalence and Non-Inferiority
  - 1.6.1.5. Objectives
  - 1.6.1.6. Basic Statistical Aspects
  - 1.6.1.7. Intermediate Data Tracking
  - 1.6.1.8. Quality of Equivalence and Non-Inferiority RCTs
  - 1.6.1.9. Ethical Aspects
  - 1.6.1.10. Post-Equivalence
- 1.6.2. Conclusions

1.7. Equivalence and Non-Inferiority CTs (II)
- 1.7.1. Therapeutic Equivalence in Clinical Practice
  - 1.7.1.1. Level 1: Direct Trials Between 2 Drugs, with Equivalence or Non-Inferiority Design

1.7.1.2. Level 2: Direct Trials Between 2 Drugs, with Statistically Significant Differences, but without Clinical Relevance
1.7.1.3. Level 3: Not Statistically Significant Trials
1.7.1.4. Level 4: Different Trials vs. a Third Common Denominator
1.7.1.5. Level 5: Trials vs. Different Comparators and Observational Studies
1.7.1.6. Supporting Documentation: Reviews, Clinical Practice Guidelines, Recommendations, Expert Opinion, Clinical Judgment
1.7.2. Conclusions
1.8. Guidelines for the Development of a Clinical Trial Protocol
1.8.1. Summary
1.8.2. Index
1.8.3. General Information
1.8.4. Justification
1.8.5. Hypothesis and Objectives of the Trial
1.8.6. Trial Design
1.8.7. Selection and Withdrawal of Subjects
1.8.8. Treatment of Subjects
1.8.9. Efficacy Assessment
1.8.10. Safety Assessment
1.8.10.1. Adverse Events
1.8.10.2. Adverse Events Management
1.8.10.3. Adverse Events Notification
1.8.11. Statistics
1.8.12. Ethical Aspects
1.8.13. Information and Consent
1.8.14. Financing and Insurance
1.8.15. Publication Policy
1.8.16. Conclusions
1.9. Non-Protocol Administrative Aspects of Clinical Trials
1.9.1. Documentation Required for the Start of the Trial
1.9.2. Subject Identification, Recruitment and Selection Records
1.9.3. Source Documents
1.9.4. Data Collection Notebooks (DCNs)
1.9.5. Monitoring
1.9.6. Conclusions
1.10. Data Collection Notebooks (DCNs)
1.10.1. Definition
1.10.2. Function
1.10.3. Importance and Confidentiality
1.10.4. Types of Data Collection Notebooks
1.10.5. Elaboration of the Data Collection Notebook
1.10.5.1. Types of Data
1.10.5.2. Order
1.10.5.3. Graphic Design
1.10.5.4. Filling in the Data
1.10.5.5. Recommendations
1.10.6. Conclusions

Module 2. Monitoring of Clinical Trials (I)

2.1. Promoter I
2.1.1. General Aspects
2.1.2. Promoters Responsibilities
2.2. Promoter II
2.2.1. Project Management
2.2.2. Non-commercial Research
2.3. Protocol
2.3.1. Definition and Content
2.3.2. Protocol Compliance
2.4. Monitoring
2.4.1. Introduction
2.4.2. Definition
2.4.3. Monitoring Objectives
2.4.4. Types of Monitoring: Traditional and Risk-Based
2.5. Clinical Trial Monitor I
2.5.1. Who can be a Monitor?
2.5.2. CRO: Clinical Research Organization
2.5.3. Monitoring Plan

2.6. Clinical Monitor II
- 2.6.1. Monitors Responsibilities
- 2.6.2. Verification of Source Documents Source Documents Verification (SDV)
- 2.6.3. Monitors Report and Monitoring Letter

2.7. Selection Visit
- 2.7.1. Researcher Selection
- 2.7.2. Aspects to take into Account
- 2.7.3. Suitability of Facilities
- 2.7.4. Visit to other Hospital Services
- 2.7.5. Deficiencies in Study Facilities and Staffing

2.8. START UP in a Clinical Research Center
- 2.8.1. Definition and Functionality
- 2.8.2. Essential Documents at the Beginning of the Trial

2.9. Initiation Visit
- 2.9.1. Objective
- 2.9.2. Preparing the Initiation Visit
- 2.9.3. Investigators File
- 2.9.4. *Investigator Meeting*

2.10. Hospital Pharmacy Initiation Visit
- 2.10.1. Objective
- 2.10.2. Investigational Drug Management
- 2.10.3. Temperature Control
- 2.10.4. General Deviation Procedure

Module 3. Monitoring of Clinical Trials (II)

3.1. Follow-Up Visit
- 3.1.1. Preparation
  - 3.1.1.1. Letter Confirming the Visit
  - 3.1.1.2. Preparation
- 3.1.2. Center Development
  - 3.1.2.1. Documentation Review
  - 3.1.2.2. SAEs
  - 3.1.2.3. Inclusion and Exclusion Criteria
  - 3.1.2.4. Collate
- 3.1.3. Research Team Training
  - 3.1.3.1. Monitoring
    - 3.1.3.1.1. Monitoring Report Preparation
    - 3.1.3.1.2. Issue Tracking
    - 3.1.3.1.3. Team Support
    - 3.1.3.1.4. Monitoring Letter
  - 3.1.3.2. Temperature
    - 3.1.3.2.1. Adequate Medication
    - 3.1.3.2.2. Reception
    - 3.1.3.2.3. Expiration
    - 3.1.3.2.4. Dispensing
    - 3.1.3.2.5. Setting Up
    - 3.1.3.2.6. Return
    - 3.1.3.2.7. Storage
    - 3.1.3.2.8. Documentation
  - 3.1.3.3. Samples
    - 3.1.3.3.1. Local and Central
    - 3.1.3.3.2. Types
    - 3.1.3.3.3. Temperature Registration
    - 3.1.3.3.4. Calibration/Maintenance Certificate

3.1.3.4. Meeting with the Research Team
3.1.3.4.1. Signature of Pending Documentation
3.1.3.4.2. Discussion of Findings
3.1.3.4.3. Re-Training
3.1.3.4.4. Corrective Actions
3.1.3.5. Review of ISF (*Investigator Site File*)
3.1.3.5.1. Clinical Investigations (CIs) and Protocols
3.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS
3.1.3.5.3. LOGs
3.1.3.5.4. Site Visit Letter
3.1.3.5.5. New Documentation
3.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)
3.1.3.6.1. Concept
3.1.3.3.2. Principal Investigator Review
3.1.3.7. Electronic Notebook

3.2. *Close-Out Visit*
3.2.1. Definition
3.2.2. Reasons for Close-Out Visits
3.2.2.1. Completion of the Clinical Trial
3.2.2.2. Not Complying with Protocol
3.2.2.3. Not Complying with Good Clinical Practices
3.2.2.4. At the Investigators Request
3.2.2.5. Low Recruitment
3.2.3. Procedures and Responsibilities
3.2.3.1. Before the Close-Out Visit
3.2.3.2. During the Close-Out Visit
3.2.3.3. After the Close-Out Visit
3.2.4. Pharmacy Close-Out Visit
3.2.5. Final Report
3.2.6. Conclusions

3.3. *Queries* Management, Database Slicing
3.3.1. Definition
3.3.2. Queries Rules
3.3.3. How are *Queries* Generated?
3.3.3.1. Automatically
3.3.3.2. By the Monitor
3.3.3.3. By an External Reviewer
3.3.4. When are *Queries* Generated?
3.3.4.1. After a Monitoring Visit
3.3.4.2. Close to Closing a Database
3.3.5. Query Status
3.3.5.1. Open
3.3.5.2. Pending Revision
3.3.5.3. Closed
3.3.6. Database Slicing
3.3.6.1. Most Frequent Database Slicing Errors
3.3.7. Conclusions

3.4. AE Management and SAE Notification
3.4.1. Definitions
3.4.1.1. Adverse Events "*Adverse Event*" (AE)
3.4.1.2. Adverse Reactions (AR)
3.4.1.3. Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR).
3.4.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR) (SUSAR)
3.4.2. Data to be Collected by the Researcher
3.4.3. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
3.4.3.1. Description
3.4.3.2. Dates
3.4.3.3. Unraveling
3.4.3.4. Intensity
3.4.3.5. Actions Taken
3.4.3.6. Causal Relationship
3.4.3.7. Basic Questions

3.4.3.7.1. Who Notifies, What is Notified, Who is Notified, How are they Notified, When are they Notified?

3.4.4. Procedures for the Communication of AE/AR with Investigational Drugs

3.4.4.1. Expedited Notification of Individual Cases

3.4.4.2. Periodic Security Reports

3.4.4.3. "Ad hoc" Security Reports

3.4.4.4. Annual Reports

3.4.5. Special Interest Events

3.4.6. Conclusions

3.5. Clinical Research Associate (CRA) Standard Operating Procedures *Standard Operating* Procedures (SOP)

3.5.1. Definition and objectives

3.5.2. Writing a SOP

3.5.2.1. Procedure

3.5.2.2. Format

3.5.2.3. Implementation

3.5.2.4. Review

3.5.3. SOP *Feasibility* and *Site Qualification Visit*

3.5.3.1 Procedures

3.5.4. SOP Initiation Visit

3.5.4.1. Procedures Prior to the Initiation Visit

3.5.4.2. Procedures During the Initiation Visit

3.5.4.3. Monitoring Initiation Visit Procedures

3.5.5. SOP Monitoring Visit

3.5.5.1. Procedures Prior to the Monitoring Visit

3.5.5.2. Procedures During the Monitoring Visit

3.5.5.3. Monitoring Letter

3.5.6. SOP for Close-Out Visit

3.5.6.1. Preparing the Close-Out Visit

3.5.6.2. Manage the Close-Out Visit

3.5.6.3. Monitoring After a Close-Up Visit

3.5.7. Conclusions

3.6. Quality Guarantee. Audits and Inspections

3.6.1. Definition

3.6.2. Legal Framework

3.6.3. Types of Audits

3.6.3.1. Internal Audits

3.6.3.2. External Audits or Inspections

3.6.4. How to Prepare an Audit?

3.6.5. Principal Findings

3.6.6. Conclusions

3.7. Protocol Deviations

3.7.1. Criteria

3.7.1.1. Non-Compliance with Inclusion Criteria

3.7.1.2. Compliance with Exclusion Criteria

3.7.2. International Classification of Functioning (ICF) Deficiencies

3.7.2.1. Correct Signatures on Documents (CI, LOG)

3.7.2.2. Correct Dates

3.7.2.3. Correct Documentation

3.7.2.4. Correct Storage

3.7.2.5. Correct Version

3.7.3. Out-Of-Window Visits

3.7.4. Poor or Wrong Documentation

3.7.5. The 5 Rights Medication Administration

3.7.5.1. Right Patient

3.7.5.2. Right Drug

3.7.5.3. Right Time

3.7.5.4. Right Dose

3.7.5.5. Right Route

3.7.6. Missing Samples and Parameters

3.7.6.1. Missing Samples

3.7.6.2. Parameter Not Performed

3.7.6.3. Sample Not Sent On Time

3.7.6.4. Time of Sample Collection

3.7.6.6. Request for Kits Out of Time

3.7.7. Information Privacy
3.7.7.1. Information Security
3.7.7.2. Reporting Security
3.7.7.3. Photo Security
3.7.8. Temperature Deviations
3.7.8.1. Register
3.7.8.2. Inform.
3.7.8.3. Act
3.7.9. Open Blinding at the Wrong Time
3.7.10. PI Availability
3.7.10.1. Not Updated in Interactive Voice Response Services (IVRS)
3.7.10.2. Not Sent on Time
3.7.10.3. Not Registered on Time
3.7.10.4. Broken Stock
3.7.11. Forbidden Medication
3.7.12. *Key and Non-Key*
3.8. Source and Essential Documents
3.8.1. Features
3.8.2. Source Documents Location
3.8.3. Source Document Access
3.8.4. Source Document Types
3.8.5. How to Correct a Source Document?
3.8.6. Source Document Retention Time
3.8.7. Main Components of the Medical History
3.8.8. Investigator's Brochure (IB)
3.9. Monitoring Plan
3.9.1. Visits
3.9.2. Frequency
3.9.3. Organization
3.9.4. Confirmation
3.9.5. Site Issues Categorization
3.9.6. Communication with Researchers
3.9.7. Research Team Training
3.9.8. Trial Master File
3.9.9. Reference Documents
3.9.10. Electronic Notebooks Remote Review
3.9.11. *Data Privacy*
3.9.12. Center Management Activities
3.10. Data Collection Notebooks
3.10.1. Concept and History
3.10.2. Timeline Compliance
3.10.3. Data Validation
3.10.4. Management of Data Inconsistencies or Queries
3.10.5. Data Exports
3.10.6. Security and Roles
3.10.7. Traceability and *Logs*
3.10.8. Report Generation
3.10.9. Notifications and Alerts
3.10.10. Electronic Notebook vs. Paper Notebook

This will provide key training 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:

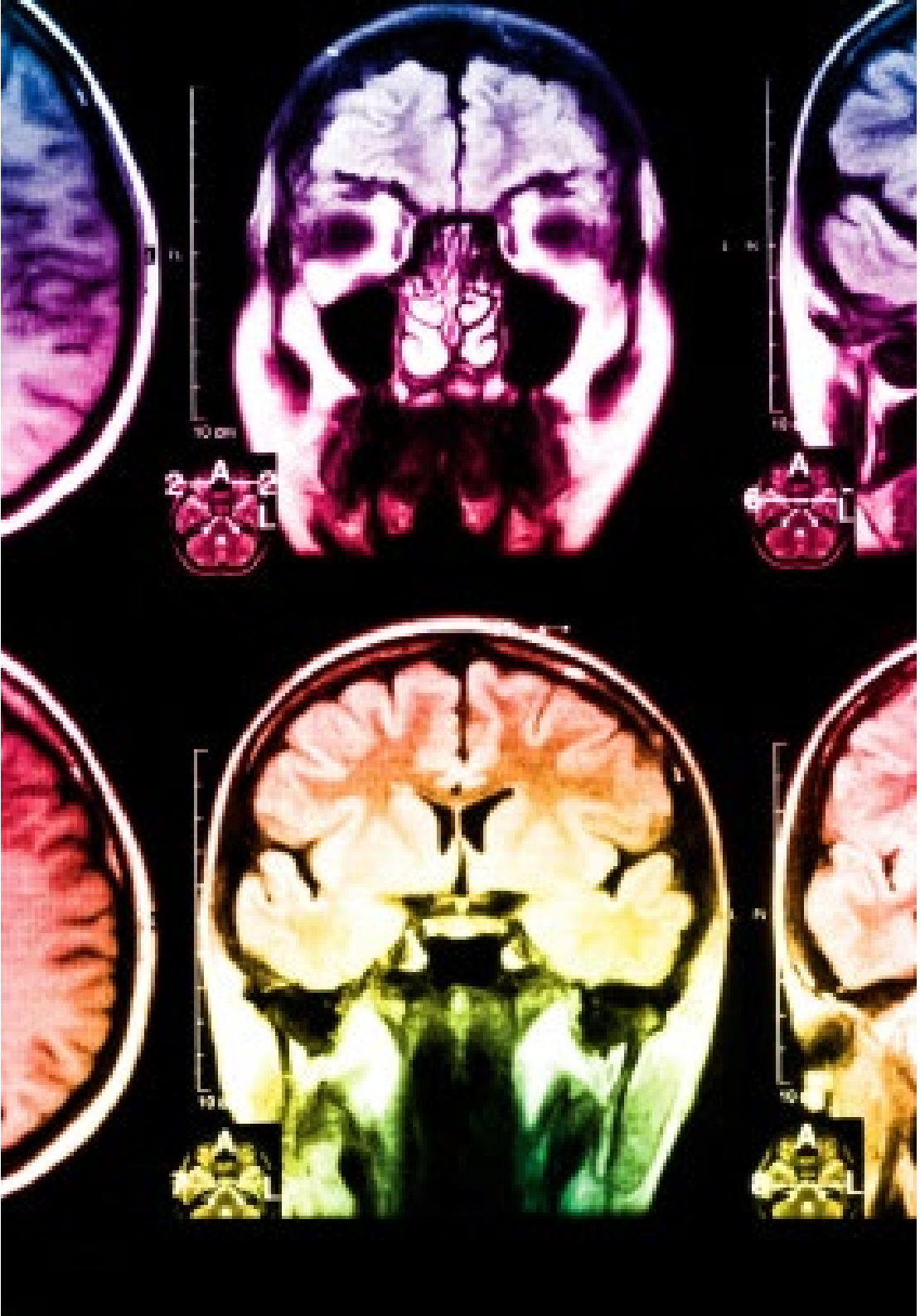
1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better 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.

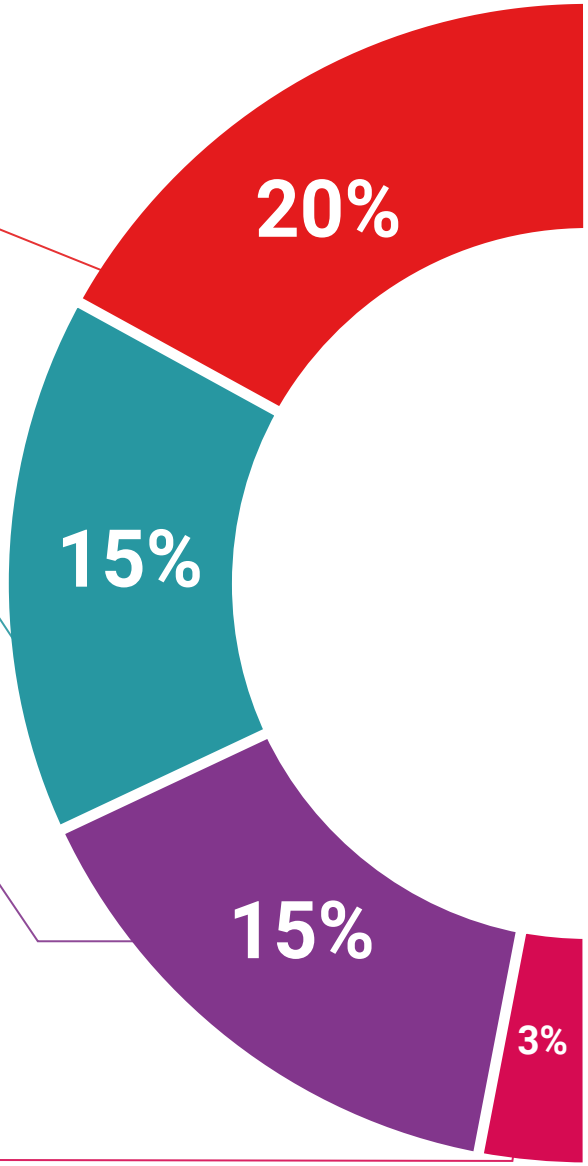
Interactive Summaries

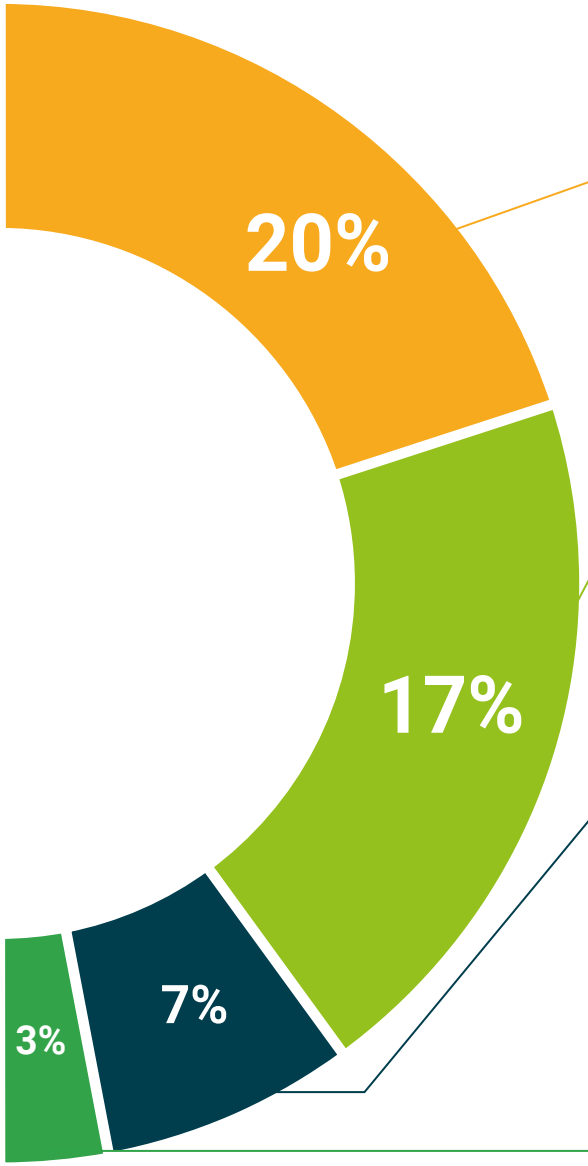
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Monitoring guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Diploma issued by TECH Global University.

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

This program will allow you to obtain your **Postgraduate Diploma in Nombre del Programa** 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** title 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 Diploma in Clinical Trials Monitoring**

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 Diploma in Clinical Trials Monitoring

This is a program of 450 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
Rector

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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Postgraduate Diploma

Clinical Trials Monitoring

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

Postgraduate Diploma
Clinical Trials Monitoring

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