Postgraduate Diploma

Clinical Trial Monitoring

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Postgraduate Diploma
Clinical Trial Monitoring

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

Website: **www.techtitute.com/us/pharmacy/postgraduate-diploma/postgraduate-diploma-clinical-trial-monitoring**

Index

01

Introduction

In Clinical Trials, the monitoring process is of great importance, since it is the ideal way to determine the validity or otherwise of the results. This specialized educational program in this field has been designed at TECH to specialize pharmacists who wish to broaden their field of action towards research, so that they acquire advanced knowledge in the field and can contribute all their expertise in future trials.

Discover what's new in Clinical Trial Monitoring and give your career a boost. This program will help you grow professionally and personally"

Pharmacology research is a fundamental task in the search for treatments to improve the health of patients. Moreover, it is a booming sector, as more and more public and private institutions have realized the need to invest in research, allocating more resources to this cause. And, therefore, there is also a new need for better prepared and qualified professionals to carry out the tasks of monitoring these investigations.

To this end, this Postgraduate Diploma offers a complete education in this field, in which the students will be able to discover from the design of the protocol from which the entire clinical trial is developed, and assess their responsibility for the verification of the adequate and effective monitoring of the clinical trial, to the close relationship that exists between the trial promoter and the monitor.

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. In addition, as it is a 100% online Postgraduate Diploma, the students are the ones who decide where and when to study, for which they only need a computer or mobile device with internet connection.

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 case studies presented by experts in Clinical Trial 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 practice
- New developments on Clinical Trials Monitoring
- Practical exercises where self-assessment can be used to improve learning
- Special emphasis on innovative methodologies in Clinical Trial 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 will allow you to specialize in Clinical Trials Monitoring until you achieve excellence in your work"

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 Clinical Trial Monitoring, you will obtain a diploma endorsed by the TECH Global University"

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

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

The teaching staff includes professionals from the Health sector, who bring their experience to this educational 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 education programmed to learn 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 professional will be assisted by an innovative interactive video system created by renowned and experienced experts in the field of Clinical Trial Monitoring.

02

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 Trial Monitoring and learn about the latest advances in the field"

General Objectives

- Establish the basic structure of a clinical trial
- Justify the difference between different types of clinical trials
- Compile the essential documents and procedures within a clinical trial
- Establish the different roles that exist in the figure of the clinical trial sponsor, their function and their relationship with the investigator's center
- Substantiate the concept of monitoring
- Analyze the content of a clinical research protocol and recognize the commitment that a good compliance with it entails
- Master the skills necessary for project development and management
- Define the process of monitoring a clinical trial, with the necessary documentation, tools and guidance for this role, taking into account the main problems that may be encountered
- Present the latest scientific advances in clinical trial monitoring tasks, with knowledge adapted to the real needs of companies in the pharmaceutical sector
- Present the wide range of tasks involved in conducting a CT and what is involved at each stage of the clinical trial
- Substantiate the practical aspects of conducting a CE and the role of the clinical trial monitor

Specific Objectives

Module 1. Clinical Trials (I)

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

Module 2. Monitoring of Clinical Trials (I)

- Disclose the types of fraud committed in clinical trials research
- Specify both the professional profile of the clinical trial monitor and the skills that must be developed to carry out the monitoring process of a clinical trial
- Establish your responsibility in the selection of the center and in the initiation of the study
- Justify the importance of the monitor in ensuring, during the trial, the correct compliance with the procedures and activities established by the protocol and the Good Clinical Practice Guidelines
- Generate knowledge on the practical aspects of visits prior to the start of the clinical trial
- Present the basis for the essential documentation for the implementation of the clinical trial at the center
- Prepare the student in the correct handling of a pre-selection visit and initiation in the research center
- Assess the involvement of the Hospital Pharmacy Service in the management, control and traceability of the medication in the study
- Justify the importance of maintaining good communication between team members involved in the development of a clinical trial

Module 3. Monitoring of Clinical Trials (II)

- Establish the basic points of a monitoring and closing visit.
- Develop the Monitoring plan and Standard Operating Procedures (SOPs) at each stage of the clinical trial
- Present a data collection notebook and specify how to keep it up to date
- Establish the data collection process to assess safety in a clinical trial. Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Reproduce the management of a monitoring visit
- Analyze the most common protocol deviations
- Establish the important documents for a clinical trial
- Submit a clinical trial monitor's guideline (Monitoring Plan)
- Present the data collection notebooks
- Develop important theoretical knowledge about closeout visits
- Establish the documentation to be prepared for closeout visits
- Specify the points to be reviewed in the closeout visits

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 participate in its design and preparation, completing the program in an interdisciplinary manner.

The leading experts in Clinical Trial Monitoring have come together to show you all their expertise 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

Teachers

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. Benito Zafra, Ana

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

D. Moreno Muñoz, Guillermo

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

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. Díaz García, Marta

- 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"
- 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

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)

Dr. Cano Armenteros, Montserrat

- Teacher of Compulsory Secondary Education (ESO) of Biology and Geology at the Azorín public high school
- Master's Degree in Clinical Trials University of Seville
- Official Master's Degree in Primary Care Research 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.

This Postgraduate Diploma 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 According to their 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-cCmmercial Research
- 1.5.1. Introduction
- 1.5.2. Start-Up of Non-Commercial Clinical Trials
- 1.5.3. Difficulties of the Independent Promoter
- 1.5.4. Promotion of Independent Clinical Research
- 1.5.5. Application for Grants for Non-Commercial Clinical Research
- 1.5.6. 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. 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 Against 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. Notification of Adverse Events
- 1.8.11. Statistics
- 1.8.12. Information and Consent
- 1.8.13. 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 NOTEBOOK (DCN)
- 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. Promoter 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. The Monitor II
2.6.1. Monitors Responsibilities
2.6.2. Verification of Source Documents Source Documents Verification (SDV)
2.6.3. Monitor's 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. Controlling Temperature
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
3.1.2.5. Research Team Training

3.1.3. Monitoring
- 3.1.3.1. Monitoring Report Preparation
- 3.1.3.2. Issue *Tracking*
- 3.1.3.3. Team Support
- 3.1.3.4. Monitoring Letter

3.1.4. Temperature
- 3.1.4.1. Adequate Medication
- 3.1.4.2. Reception
- 3.1.4.3. Expiration
- 3.1.4.4. Dispensing
- 3.1.4.5. Setting Up
- 3.1.4.6. Return
- 3.1.4.7. Storage
- 3.1.4.8. Documentation

3.1.5. Samples
- 3.1.5.1. Local and Central
- 3.1.5.2. Types
- 3.1.5.3. Temperature Registration
- 3.1.5.4. Calibration/Maintenance Certificate

3.1.6. Meeting with the Research Team
- 3.1.6.1. Signature of Pending Documentation
- 3.1.6.2. Discussion of Findings
- 3.1.6.3. Re-Training
- 3.1.6.4. Corrective Actions

3.1.7. Review of ISF (*Investigator Site File*)
- 3.1.7.1. Clinical Investigations (CIs) and Protocols
- 3.1.7.2. New Approvals from the Ethics Committee and the AEMPS
- 3.1.7.3. LOGs
- 3.1.7.4. Site Visit Letter
- 3.1.7.5. New Documentation

3.1.8. Suspected Unexpected Serious Adverse Reactions (SUSARs)
- 3.1.8.1. Concept
- 3.1.8.2. Principal Investigator Review

3.1.9. 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. Query *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. Causality 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) (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 Closing 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
- 3.6.3. Types of Audits
  - 3.6.3.1. Internal Audits
  - 3.6.3.2. External Audits or Inspections
- 3.6.4. How 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. Report 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 (F)
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

05

Methodology

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

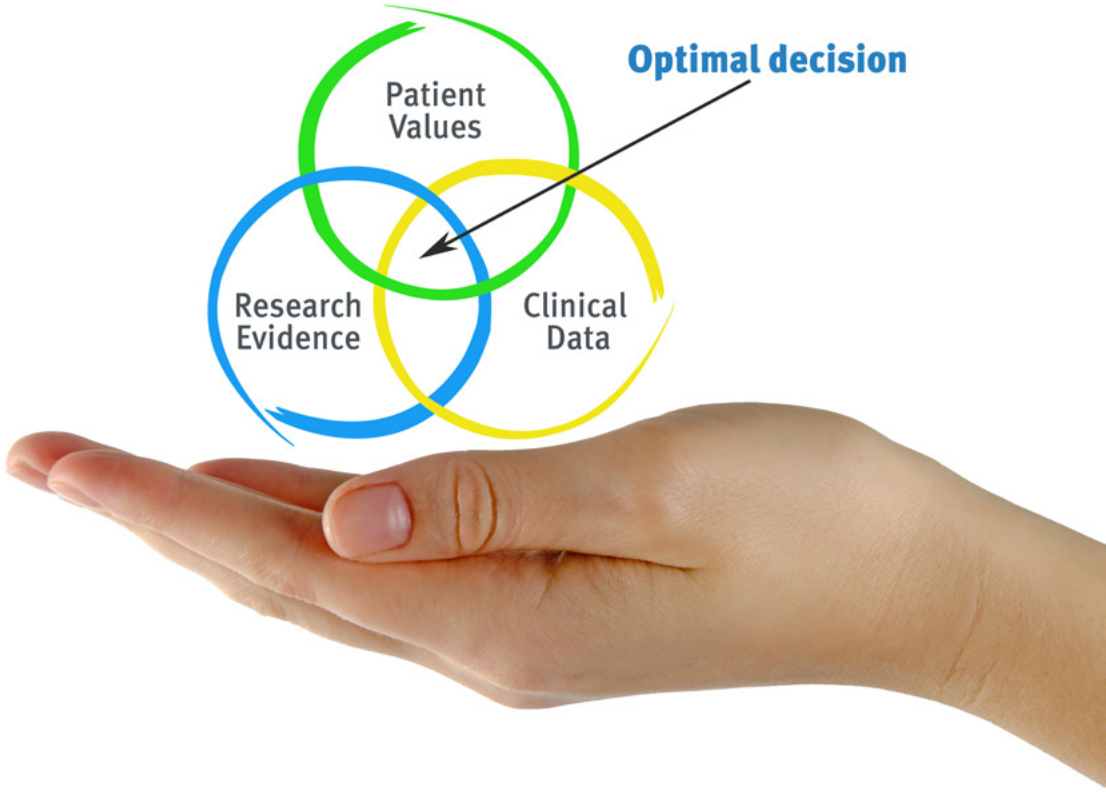
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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:

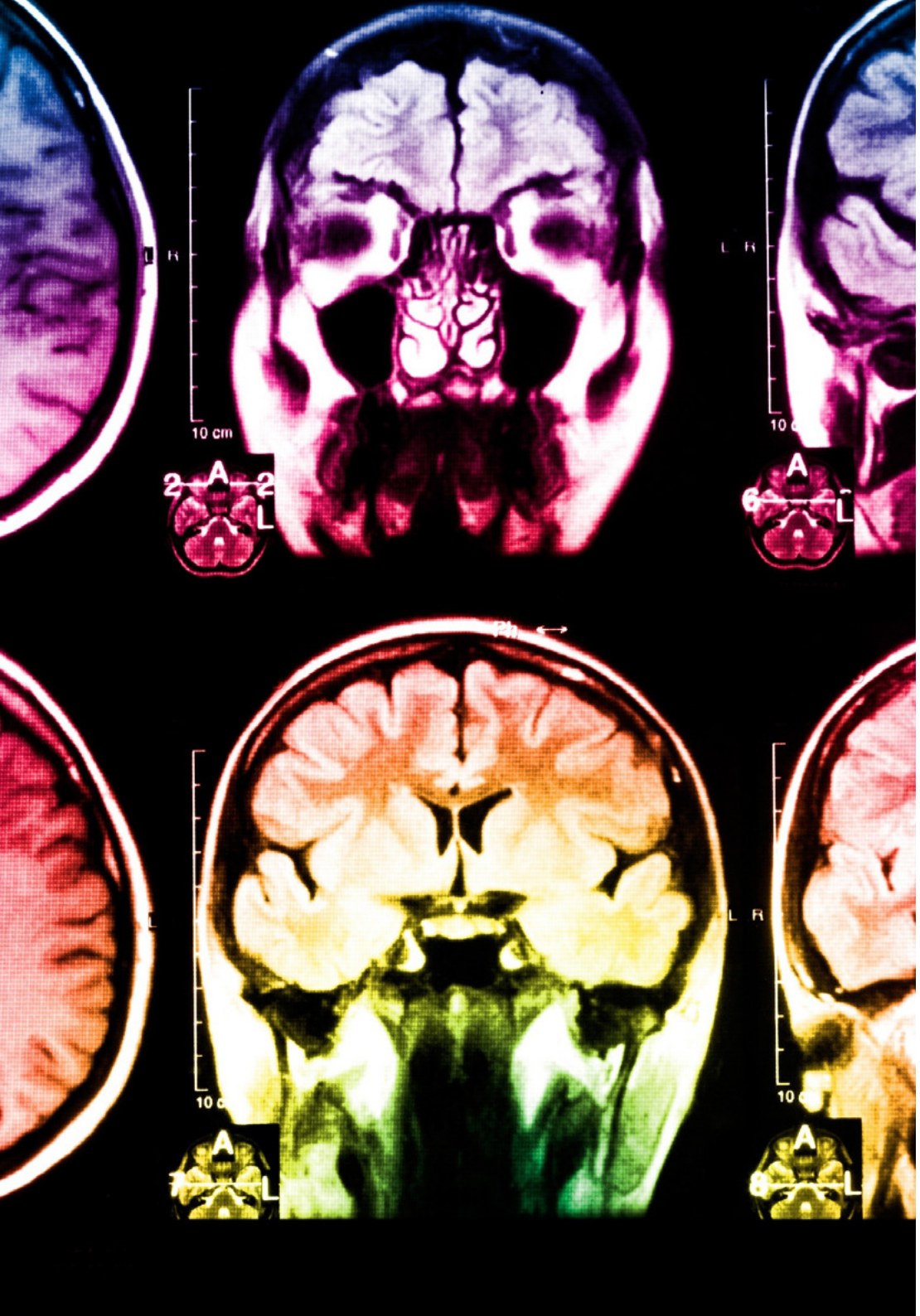
1. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts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

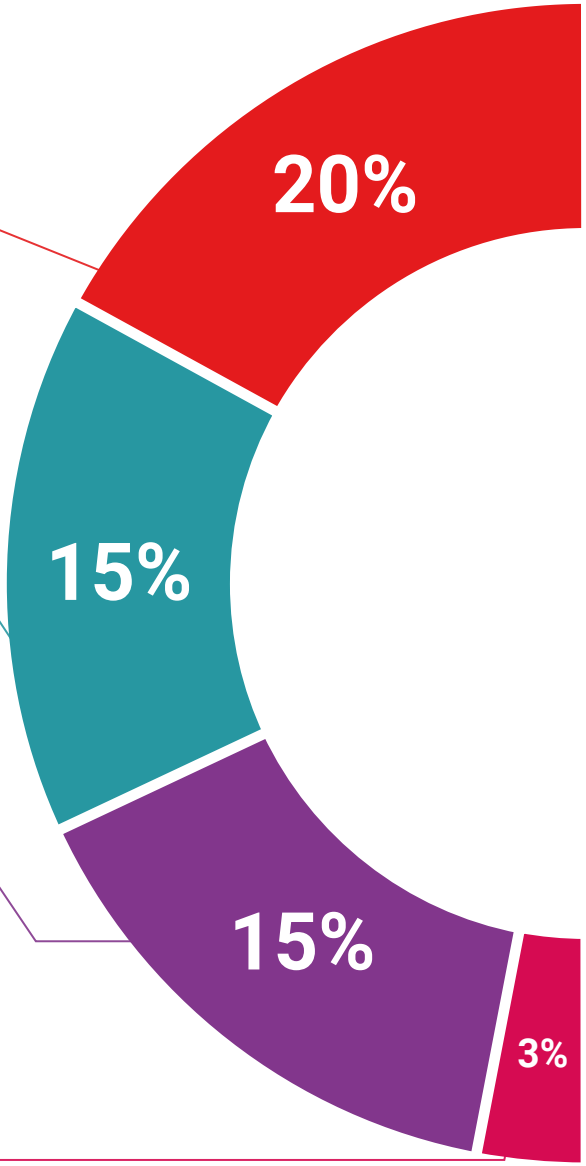
Interactive Summaries

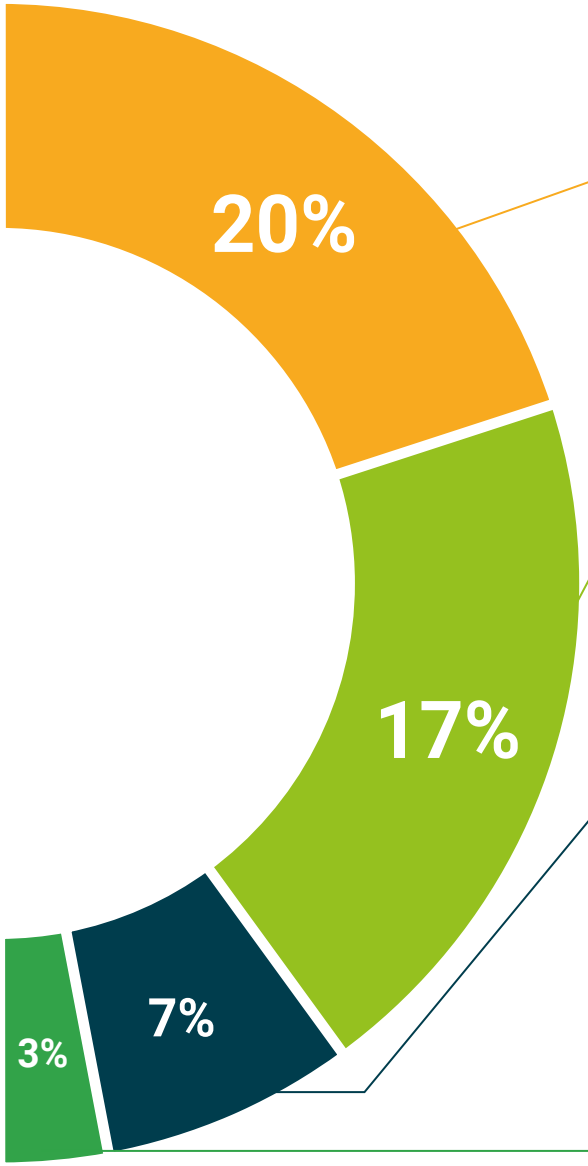
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Diploma in Clinical Trial 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 private qualification will allow you to obtain a **Postgraduate Diploma in Clinical Trial Monitoring** 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.

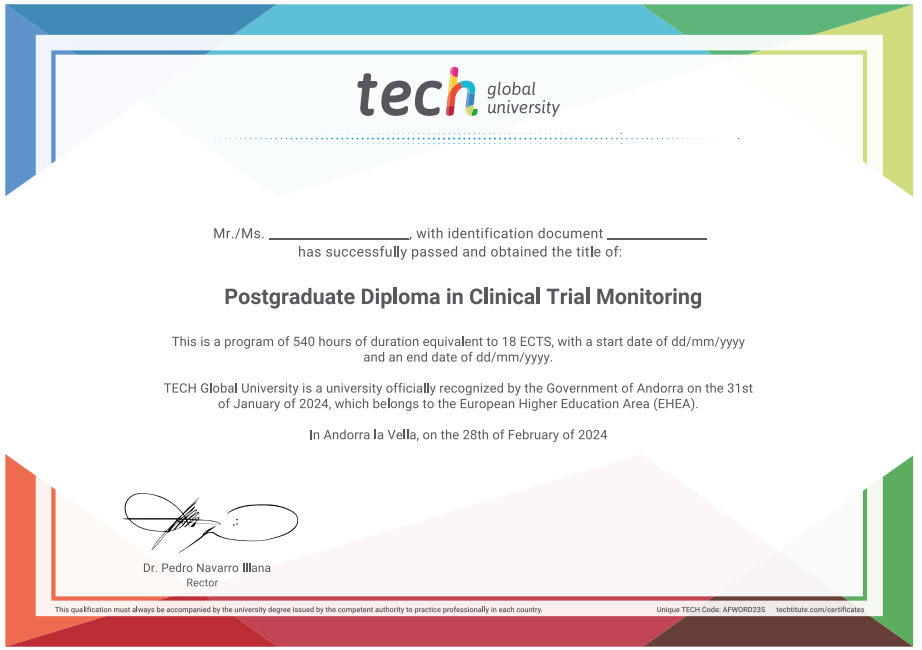
This **TECH Global University** private qualification is a European program of continuing education and professional updating that guarantees the acquisition of competencies in its area of knowledge, providing a high curricular value to the student who completes the program.

Title: **Postgraduate Diploma in Clinical Trial 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 Clinical Trial Monitoring

This is a program 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
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 Trial Monitoring

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

Postgraduate Diploma
Clinical Trial Monitoring

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