Postgraduate Diploma
Clinical Trial Monitoring for Nursing

tech technological university

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Postgraduate Diploma
Clinical Trial Monitoring for Nursing

- Modality: **online**
- Duration: **6 months**
- Certificate: **TECH Technological University**
- Dedication: **16h/week**
- Schedule: **at your own pace**
- Exams: **online**

Website: **www.techtitute.com/pk/nursing/postgraduate-diploma/postgraduate-diploma/clinical-trial-monitoring-nursing**

Index

01

Introduction

Clinical Trial Monitoring allows validating the results obtained in these tests, so that it can be determined whether a work is effective or not. For this, it is necessary to have highly prepared professionals with sufficient skills to develop this work successfully. This program aims to prepare nurses in this field so that they can give a boost to their profession and discover a new field of work.

Investing in research is important, but so is having specialized professionals" For this reason, at TECH we have designed this very complete program"

Clinical research is essential in order to find new drugs to control and cure newly emerging diseases that do not have a cure or are increasingly resistant to existing drugs. Therefore, it is essential to continue preparing in this field, which will allow nurses to specialize in Clinical Trial Monitoring for Nursing.

Clinical Trial Monitoring is one of the fundamental aspects of research. This Postgraduate Diploma defines the figure of the promoter, an essential element for the design and conduct of research. To this end, 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 sponsor's responsibility is assessed in relation to the verification of the adequate and effective monitoring of the clinical trial, thereby establishing the close relationship between the sponsor and the monitor.

In this way, 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 the Good Clinical Practice standards and the requirements of the protocol.

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 for Nursing** contains the most complete and up-to-date scientific program on the market. Its most notable features are:

- The development of case studies presented by experts in Clinical Trial Monitoring. for Nursing
- 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
- What's New in Clinical Trial Monitoring for Nurses?
- Practical exercises where self-assessment can be used to improve learning
- Its special emphasis on innovative methodologies in Clinical Trial Monitoring for Nursing
- 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 enable you to learn about Clinical Trial Monitoring for Nurses 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 for Nursing, you will obtain a qualification endorsed by TECH"

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

This 100% online Postgraduate 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 Health sector, who bring their experience to this educational program, as well as renowned specialists from leading societies and prestigious universities.

Its multimedia content, developed with the latest educational technology, will allow the professional a situated and contextual learning, that is, a simulated environment that will provide an immersive learning programmed to prepare for real situations.

The design of this program focuses on problem-based learning, by means of which the healthcare professional must try to solve the different professional practice situations that arise throughout the academic program. To do so, the professional will be assisted by an innovative interactive video system developed by recognized experts in the field of Clinical Trial Monitoring for Nurses with extensive experience.

02

Objectives

The Postgraduate Diploma in Clinical Trial Monitoring for Nursing 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 learn about Clinical Trial Monitoring for Nursing and delve into 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 research 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)
- Analyze the variety of avenues for the development and funding of non-commercial research
- Disclose the types of fraud committed in clinical trials research

Module 2. Monitoring of Clinical Trials I

- 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 (SOP) 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 Event and Serious Adverse Event
- 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 for Nursing 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
- Degree in Pharmacy, Complutense University of Madrid with a diploma for obtaining an Honorary Degree
- 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

D. Moreno Muñoz, Guillermo

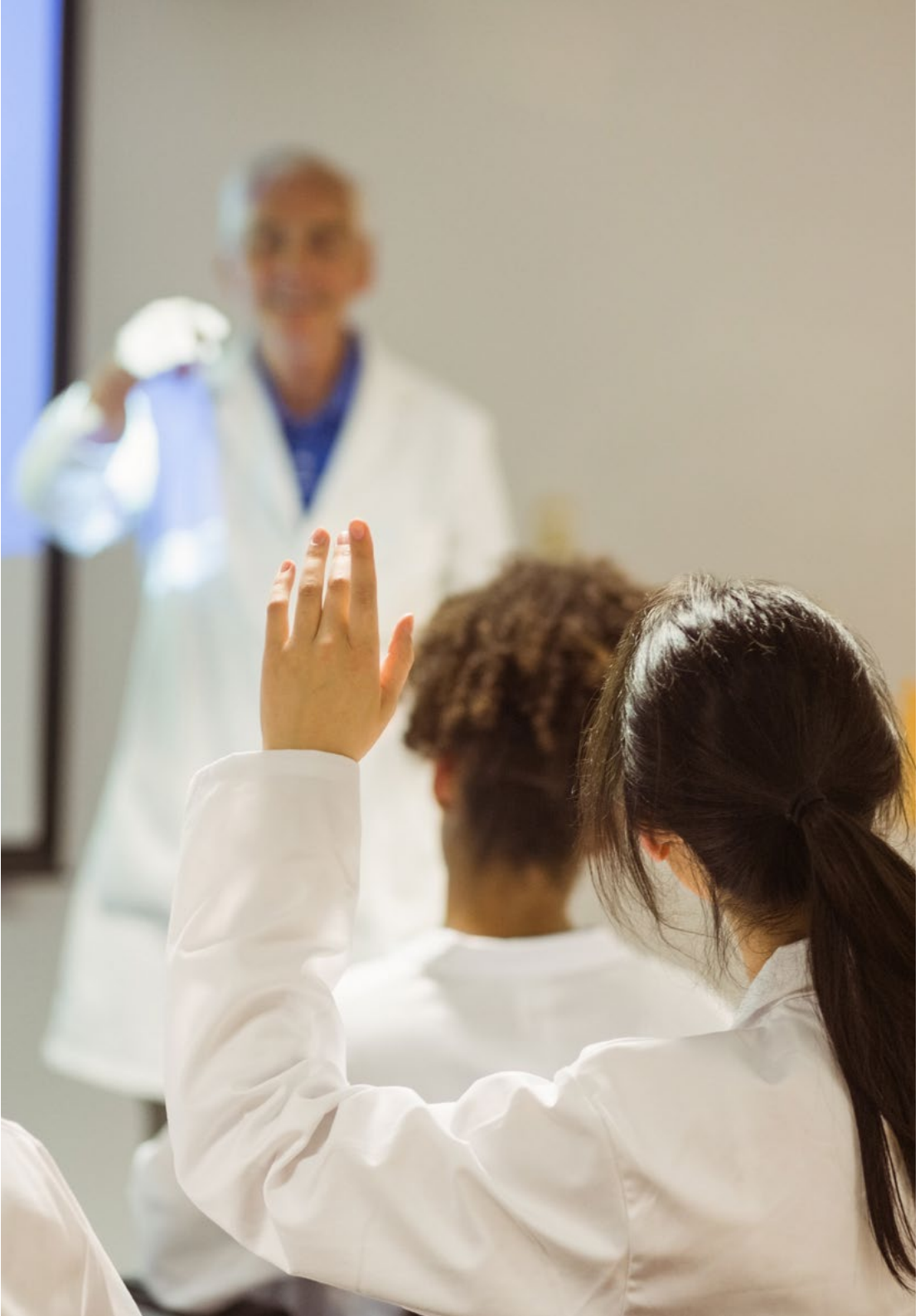
- Coordinator of Clinical Trials and Observational Studies in the Cardiology Intensive Care Unit of the Cardiology Service of the 12 de Octubre Hospital
- Collaborating Professor of Pharmacology and Nurse Prescription of the Department of Nursing, Physiotherapy and Podiatry of the UCM
- Degree in Nursing 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. 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

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

Ms. De Torres Pérez, Diana

- Trial Coordinator at the 12 de Octubre University Hospital, Cardiology Service (Hemodynamics and Arrhythmias)
- 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 s Degree in ESAME Pharmaceutical- Business School

Dr. Cano Armenteros, Montserrat

- Teacher of Compulsory Secondary Education (ESO) of Biology and Geology at the Azorín public high school
- Master'a 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 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 EECC 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 EECC 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. Information and Consent
- 1.8.13. Financing and Insurance
- 1.8.14. Publication Policy
- 1.8.15. 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. 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. 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. Initial Visit in Hospital Pharmacy
- 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. SAE
  - 3.1.2.3. Inclusion and Exclusion Criteria
  - 3.1.2.4. Collate
- 3.1.3. Research Team Training
  - 3.1.3.1. Monitoring
    - 6.1.3.1.1. Monitoring Report Preparation
    - 3.1.3.1.2. Issue Tracking
    - 6.1.3.1.3. Team Support
    - 3.1.3.1.4. Monitoring Letter
  - 3.1.3.2. Temperature
    - 6.1.3.2.1. Adequate Medication
    - 3.1.3.2.2. Reception
    - 6.1.3.2.3. Expiration
    - 3.1.3.2.4. Dispensing
    - 6.1.3.2.5. Setting Up
    - 3.1.3.2.6. Returns
    - 6.1.3.2.7. Storage
    - 3.1.3.2.8. Documentation
  - 3.1.3.3. Samples
    - 6.1.3.3.1. Local and Central
    - 3.1.3.3.2. Types
    - 6.1.3.3.3. Temperature Registration
    - 3.1.3.3.4. Calibration/Maintenance Certificate
  - 3.1.3.4. Meeting with the Research Team
    - 6.1.3.4.1. Signature of Pending Documentation
    - 3.1.3.4.2. Discussion of Findings
    - 6.1.3.4.3. Re-Training
    - 3.1.3.4.4. Corrective Actions
  - 3.1.3.5. Review of ISF (Investigator Site File)
    - 6.1.3.5.1. Clinical Investigations (CIs) and Protocols
    - 3.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS
    - 6.1.3.5.3. LOGs
    - 3.1.3.5.4. Site Visit Letter
    - 6.1.3.5.5. New Documentation

3.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)
6.1.3.6.1. 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
6.4.3.7.1. 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 Safety 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 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
3.6.2. Types of Audits
3.6.2.1. Internal Audits
3.6.2.2. External Audits or Inspections
3.6.3. How Prepare an Audit
3.6.4. Principal Findings
3.6.5. 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 (F)
- 3.9.3. Organisation
- 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

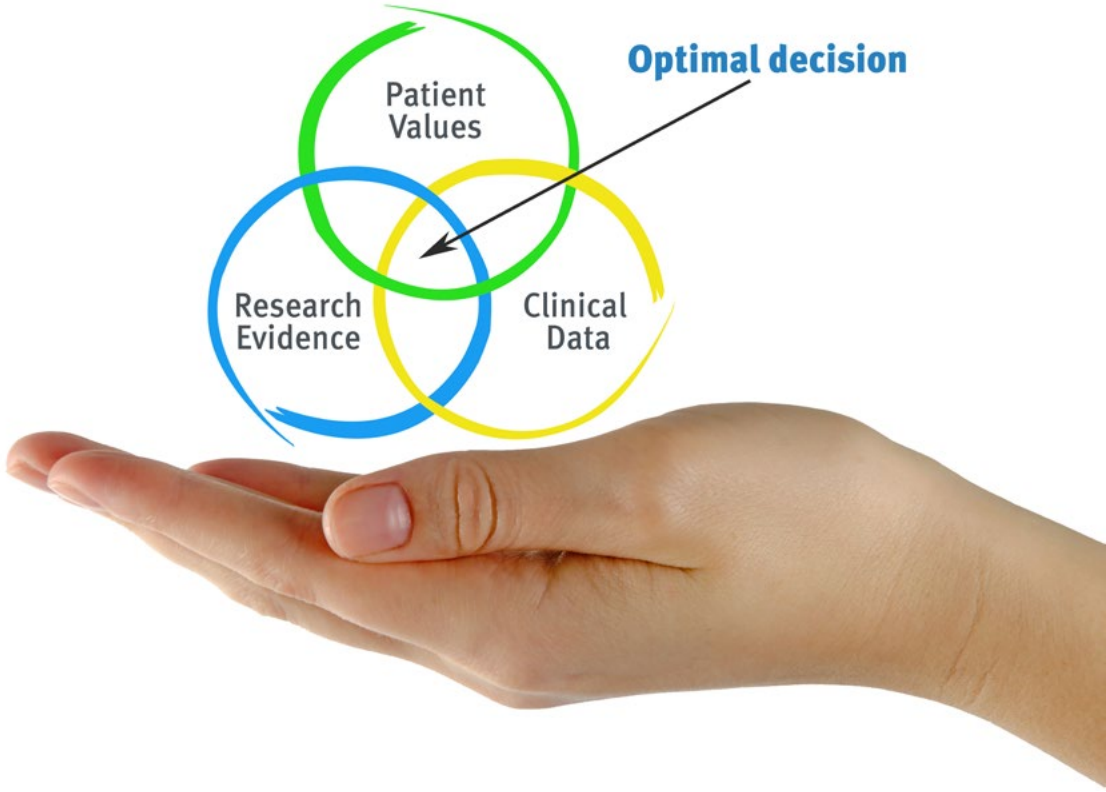
This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning.**
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** 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 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:

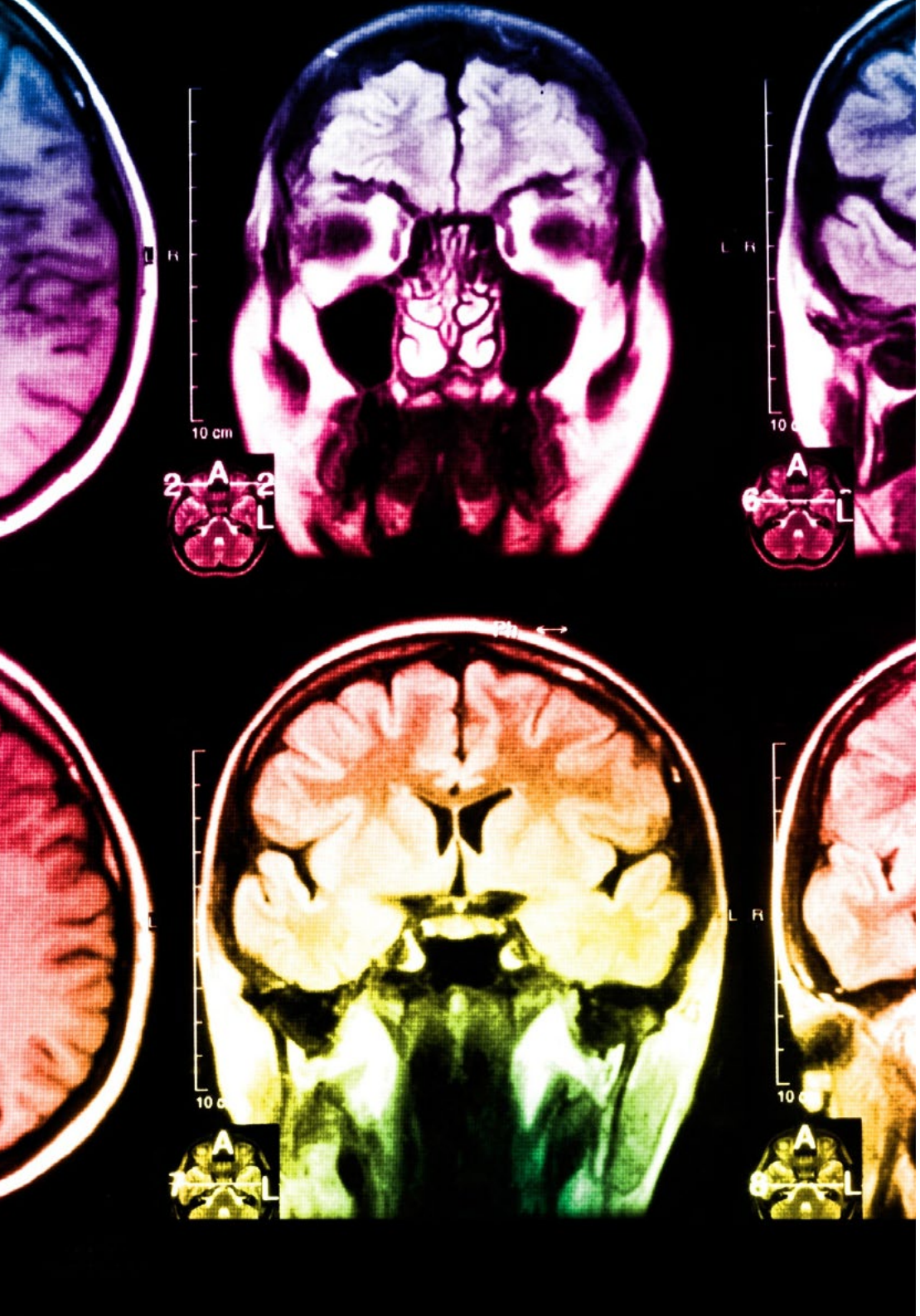
1. Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into 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

TECH effectively combines the Case Study methodology with a 100% online learning system based on repetition, which combines 8 different teaching elements in each lesson.

We enhance the Case Study with the best 100% online teaching method: Relearning.

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.

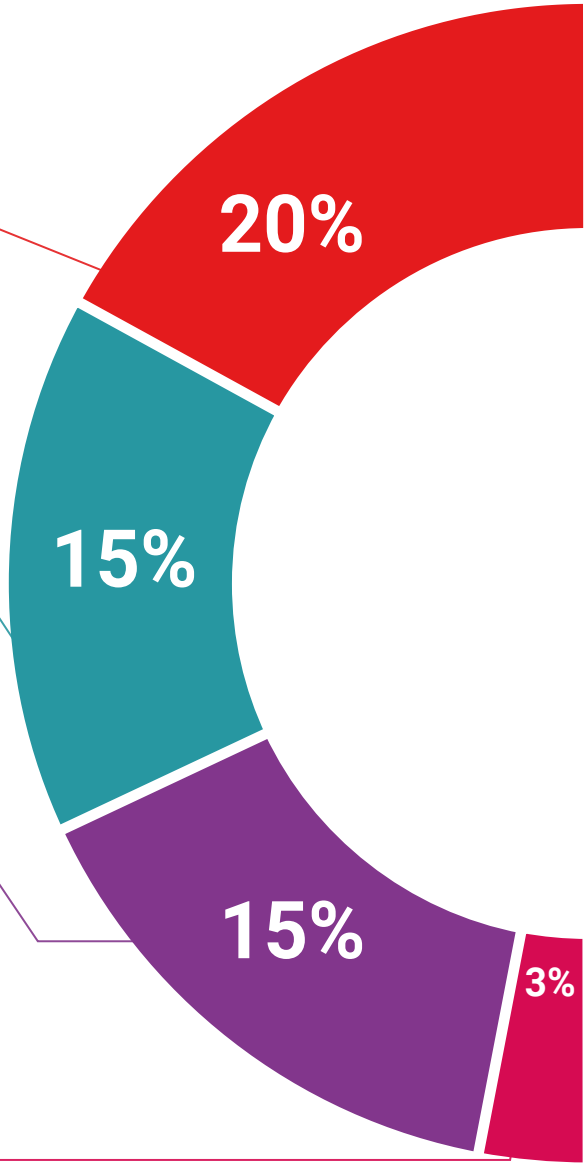
Interactive Summaries

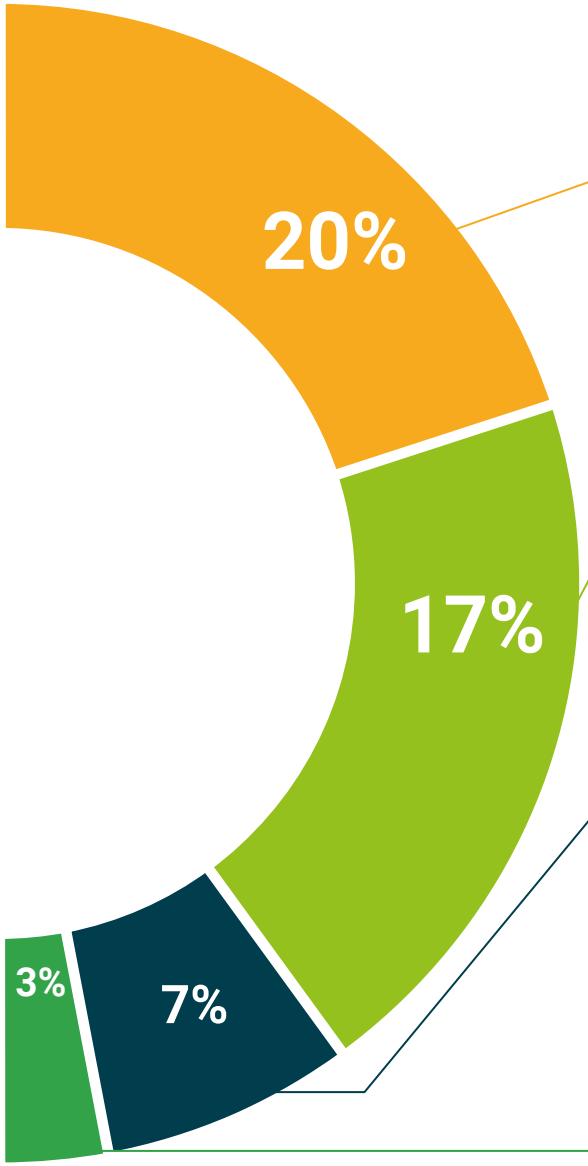
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Clinical Trials Monitoring for 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 **Postgraduate Diploma in Clinical Trials Monitoring for Nursing** contains the most complete and up-to-date scientific program on the market.

After you have passed the evaluations, you will receive your corresponding **Postgraduate Diploma** issued by **TECH Technological University** via tracked delivery*.

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

Title: **Postgraduate Diploma in Clinical Trials Monitoring for Nursing**

Official Nº of hours: **450 h.**


tech technological university

Awards the following

CERTIFICATE

to

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

For having passed and accredited the following program

POSTGRADUATE DIPLOMA

in

Clinical Trial Monitoring for Nursing

This is a qualification awarded by this University, equivalent to 450 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

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

June 17, 2020

Tere Guevara Navarro
Dean

This qualification must always be accompanied by the university degree issued by the competent authority to practice professionally in each country. Unique TECH Code: AFWORD23S techtitute.com/certificates

*Apostille Convention. In the event that the student wishes to have their paper certificate issued with an apostille, TECH EDUCATION will make the necessary arrangements to obtain it, at an additional cost.

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Postgraduate Diploma
Clinical Trials Monitoring for Nursing

- Modality: **online**
- Duration: **6 months**
- Certificate: **TECH Technological University**
- Dedication: **16h/week**
- Schedule: **at your own pace**
- Exams: **online**

Postgraduate Diploma
Clinical Trial Monitoring for Nursing

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