Professional Master's Degree

Management and Monitoring of Clinical Trials for Nursing

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Professional Master's Degree
Management and Monitoring of Clinical Trials for Nursing

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

Website: **www.techtitute.com/us/nursing/professional-master-degree/master-management-monitoring-clinical-trials-nursing**

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01

Introduction

The creation of new drugs allows us to survive new pathologies, diseases for which there are no effective treatments, or which have shown resistance to existing drugs. Therefore, research in this field is essential to find effective drugs against the pathologies that affect human beings. In this case, TECH presents a very complete education on Clinical Trial Management and Monitoring for Nursing, since research is a multidisciplinary field that depends on different sectors.

Improving the patient's quality of life is one of the objectives of healthcare and, to achieve this, we must make every effort in research"

Research is a field that is growing every day, thanks to the efforts of public bodies and private institutions to invest in this field, achieving the appearance of successful drugs that allow the survival of patients fighting against diseases that until now had no cures or treatments that would allow them to improve their quality of life in the face of chronic illnesses.

It is a multidisciplinary field in which professionals from different health fields participate. Therefore, in this case, TECH has designed this comprehensive program specifically for nurses, with the aim of acquiring specialized knowledge on Management and Monitoring of Clinical Trials for Nursing, through a theoretical and practical education provided by professionals with extensive experience.

The teaching team of this Professional Master's Degree has made a careful selection of topics, useful for experienced professionals working in the healthcare field. This program specializes the nurse in the field of clinical trials, being able to access the pharmaceutical industry field in the management and monitoring of clinical studies.

In addition, this program includes the most advanced web 2.0 communication tools, which support working methods that encourage interaction among students, the exchange of information and constant and active participation.

As it is an online program, the student is not constrained by fixed schedules or the need to move to another physical location, but rather, they can access the contents at any time of the day, allowing them to balance their professional or personal life with their academic life as they please.

This **Professional Master's Degree in Management and Monitoring of Clinical Trials for Nursing** 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 Trials
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- New developments in Clinical Trials
- Practical exercises where self-assessment can be used to improve learning
- Special emphasis on innovative methodologies in Clinical Trials
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- Content that is accessible from any fixed or portable device with an internet connection

Expand your knowledge through this Professional Master's Degree that will allow you to specialize until you achieve excellence in this field"

This Professional Master's Degree is the best investment you can make when selecting an up-to-date program for two for Nursing reasons: In addition to updating your knowledge in Management and Monitoring of Clinical Trials for Nursing, you will obtain a degree from TECH Technological University"

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

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

The teaching staff includes professionals belonging to the field of health, who bring to this program the experience of their work, as well as recognized specialists from reference 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.

The design of this program is focused on Problem-Based Learning, so 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 Management and Monitoring of Clinical Trials for Nursing, and with great experience.

02

Objectives

The Management and Monitoring of Clinical Trials for Nursing program is oriented to facilitate the performance of the research professional with the latest advances and most innovative treatments in the sector.

Thanks to this Professional Master's Degree, you will be able to specialize in Management and Monitoring of Clinical Trials for Nursing 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
- 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
- Develop the clinical trial drug circuit from the point of view of the pharmacy service
- Analyze universal ethical principles
- Compile the rights and duties of the different parties involved in clinical trials
- 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 monitoring process of a clinical trial, having 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 CE and what is involved at each stage of the clinical trial
- Explain the practical aspects of conducting a CT and the role of the monitor
- Analyze the importance of the role of the trial coordinator in clinical research
- Specify the main functions of the research team and their involvement with the patient
- Establish the main components of a clinical trial and observational study
- Develop specialized knowledge about the variety of tasks they have to perform during the development of the study
- Establish tools and strategies to address the different problems that arise during the clinical trial, in order to obtain satisfactory results in patient monitoring
- Develop knowledge that provides a basis or opportunity for originality in the development and/or application of ideas, often in a research context
- Apply the acquired knowledge and resolution skills in the development of protocols
- Structure statistical methods and techniques
- Communicate and transmit statistical results through the preparation of different types of reports, using terminology specific to the fields of application
- Compile, identify and select sources of public biomedical information, from international agencies and scientific organizations, on the study and dynamics of populations
- Analyze the scientific method and work on skills in the handling of information sources, bibliography, protocol elaboration and other aspects considered necessary for the design, execution and critical assessment
- Demonstrate logical thinking and structured reasoning in determining the appropriate statistical technique

Specific Objectives

Module 1. Drug research and development

- 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. 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)
- Disclose the types of fraud committed in clinical trials research

Module 3. Clinical Trials II

- Specify the different activities related to sample management (reception, dispensing, custody, etc.) in which the Pharmacy team is involved
- Establish the procedures and techniques involved in the safe handling of samples during their preparation
- Analyze the development of a clinical trial through the vision and participation of the hospital pharmacist
- Detail informed consent
- Know the physiological differences between children and adults

Module 4. Bioethics and Regulations

- 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

Module 5. 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 6. 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

Module 7. Coordination of Clinical Trials I

- Specify the mandatory documents and forms that must be included in the researcher's file
- Establish how to best manage the archive at the beginning, during and at the end of the study: storing, updating and ordering documentation
- Define the steps to be followed to complete the documents and forms for the researchers file

Module 8. Coordination of Clinical Trials II

- Substantiate the necessary skills to be developed in order to perform the work of the trial coordinator
- Define the organization and preparation of both the research team and the center for their inclusion in a clinical trial, managing the CV, good clinical practices, suitability of the facilities, etc.
- Reproduce the tasks to be performed in both a clinical trial and an observational study
- Analyze a clinical trial protocol through theoretical and practical examples
- Determine the work of a coordinator in their work center under a clinical trial protocol (patients, visits, tests)
- Develop the skills necessary for the use of a data collection notebook: data entry, query resolution and sample processing
- Compile the different types of pharmacological treatments that can be used in a clinical trial (placebo, biological) and their management

Module 9. Follow-up of Patients in Clinical Trials

- Specify the daily practices of patient care in specialized care, establishing the management of clinical trial procedures, protocols and databases
- Analyze the materials used during the development of the studies
- Assess the causes of patient dropout within a study and establish strategies for patient retention
- Assess how monitoring loss occurs in patients within a study, examine its causes and explore possibilities for resumption of monitoring
- Compile the different risk factors that can lead to poor adherence to treatment, and apply strategies for improving and monitoring adherence to treatment
- Analyze the different presentations of medications in order to manage the signs and symptoms, as well as the adverse reactions that may derive from taking medication
- Establish the different tools to calculate the attendance and monitoring of visits

Module 10. Biostatistics

- Identify and incorporate in the advanced mathematical model, which represents the experimental situation, those random factors involved in a high-level biosanitary study
- Design, collect and clean a data set for subsequent statistical analysis
- Identify the appropriate method for determining the sample size
- Distinguish between different types of studies and choose the most appropriate type of design according to the research objective
- Communicate and transmit statistical results correctly, through the preparation of reports
- Acquire an ethical and social commitment

03

Skills

After passing the assessments of the Professional Master's Degree in Management and Monitoring of Clinical Trials for Nursing, professionals will have acquired the necessary skills for a quality and up-to-date praxis based on the most innovative teaching methodology.

Learn about the new tools in the Management and Monitoring of Clinical Trials for Nursing to provide a better care to your patients"

General Skills

- Develop all phases of a clinical trial
- Monitor patients participating in research projects
- Perform process monitoring

We offer you the opportunity to learn in this fast-moving field”

Specific Skills

- Publish research results in different formats
- Read scientific publications critically
- Identify the different types of clinical trials
- Develop a safety surveillance plan for marketed drugs
- Establish research protocols for clinical trials
- Develop clinical trials with the collaboration of the hospital pharmacist
- Define the physiological differences between children and adults
- Analyze a Clinical Trial in the setting of a Urology Department
- Recognize and comply with the rules governing clinical trials
- Know the specific regulations and apply them in clinical trials
- Ensure the safety of participants in clinical trials
- Present the documentation for the clinical trial start-up and correctly handle the previous visits to the research center
- Communicate correctly with the other members of the research team
- Manage monitoring visits and closure of the clinical trial
- Perform and present the guidelines of a clinical trial monitor
- Describe the overall monitoring process
- Identify all the documents to be contained in the researchers file
- Know how to manage the file with all the necessary documentation for clinical trials
- Carry out protocols for clinical trials through examples
- Identify and know how to use the different drugs that can be used in clinical trials
- Identify the causes of dropout of patients participating in research cases
- Assess the treatments and possible adverse effects caused by some drugs
- Collect clinical trial data for further analysis
- Communicate the results of clinical trials through the most appropriate means in each case

04

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 Management and Monitoring of Clinical Trials 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

Dr. Dompablo Tobar, Mónica

- Researcher at the Psychiatry Department of the Hospital Universitario 12 de Octubre
- Degree in Psychology from the Universidad Autónoma de Madrid
- PhD in Psychology from the Complutense University of Madrid. Outstanding Cum Laude

Dr. Bravo Ortega, Carlos

- Coordinator of clinical trials in the Clinical Nephrology Service of the 12 de Octubre Hospital
- Degree in Biology from the University of Alcalá de Henares
- Master's Degree in Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

Ms. Valtueña Murillo, Andrea

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

Ms. Santacreu Guerrero, Mireia

- Nurse Clinical Trials Coordinator at the HIV Unit of the 12 de Octubre University Hospital, Madrid
- Degree in Nursing from the European University of Madrid
- Master's Degree in Nursing Management from the same University

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

Dr. 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. 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

Dr. Rodríguez Jiménez, Roberto

- Director of the Inpatient Unit, Day Hospital, Emergency Department, Electroconvulsive Therapy Program and Psychosis Program
- Degree in Medicine and Surgery
- Degree in Psychology
- Master's Degree in Psychotherapy
- Doctor in Psychiatry
- Alcoholism Specialist

Ms. Jiménez Fernández, Paloma

- Coordinator of clinical trials in the Rheumatology Service of the 12 de Octubre Hospital
- Graduate in Pharmacy from the Complutense University of Madrid
- Master's Degree in Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

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. Martín-Arriscado Arroba, Cristina

- Member of the Drug Research Ethics Committee of the 12 de Octubre University Hospital
- Biostatistics at the Research and Scientific Support Unit of the 12 de Octubre University Hospital (i+12) and the Clinical Research Units and Clinical Trials Platform (SCReN)

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

Ms. Bermejo Plaza, Laura

- Coordinator of Clinical Trials at the HIV Unit of the 12 de Octubre University Hospital of Madrid
- Degree in Nursing from the Complutense University of Madrid

Ms. Gómez Abecia, Sara

- Clinical Research Project Manager
- Biology Graduate
- Master in Clinical in Trials

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

Mr. Sánchez Ostos, Manuel

- Study Coordinator of Clinical Trials, IMIBIC
- Master's Degree in Clinical Trial Monitoring and Pharmaceutical Development. University of Nebrija (Madrid)
- Professional Master's Degree in Biotechnology. University of Córdoba
- Master's Degree in Teacher Training. University of Córdoba
- Degree in Biology. University of Córdoba

Ms. Pérez Indigua, Carla

- Research Nurse in the Clinical Pharmacology Service of the San Carlos Clinical Hospital
- Degree in Nursing. Complutense University of Madrid
- Master's Degree in Research Methodology in Health Care from the UCM
- D. candidate in Health Care. Complutense University of Madrid
- Professor of the subject "Ethics of research with human beings" in the Professional Master's Degree of Applied Ethics of the Faculty of Philosophy of the UCM

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 Professional Master's Degree contains the most complete and up-to-date scientific program on the market"

Module 1. Drug research and development

1.1. Development of New Drugs
- 1.1.1. Introduction
- 1.1.2. Development Phases of New Drugs
- 1.1.3. Discovery Phase
- 1.1.4. Preclinical Phase
- 1.1.5. Clinical Phase
- 1.1.6. Approval and Registration

1.2. Discovery of an Active Substance
- 1.2.1. Pharmacology
- 1.2.2. Seeding Trials
- 1.2.3. Pharmacological Interventions

1.3. Pharmacokinetics
- 1.3.1. Methods of Analysis
- 1.3.2. Absorption
- 1.3.3. Distribution
- 1.3.4. Metabolism
- 1.3.5. Excretion

1.4. Toxicology
- 1.4.1. Single Dose Toxicity
- 1.4.2. Repeated Dose Toxicity
- 1.4.3. Toxicokinetics
- 1.4.4. Carcinogenicity
- 1.4.5. Genotoxicity
- 1.4.6. Reproductive Toxicity
- 1.4.7. Tolerance
- 1.4.8. Dependency

1.5. Regulation of Drugs for Human Use
- 1.5.1. Introduction
- 1.5.2. Authorization Procedures
- 1.5.3. How a Drug is Evaluated: Authorization Dossier
- 1.5.4. Technical Data Sheet, Package Leaflet and EPAR
- 1.5.5. Conclusions

1.6. Pharmacovigilance
- 1.6.1. Pharmacovigilance in Development
- 1.6.2. Pharmacovigilance in Marketing Authorization
- 1.6.3. Post-Authorization Pharmacovigilance

1.7. Uses in Special Situations
- 1.7.1. Introduction
- 1.7.3. Examples:

1.8. From Authorization to Commercialization
- 1.8.1. Introduction
- 1.8.2. Drug Financing
- 1.8.3. Therapeutic Positioning Reports

1.9. Special Forms of Regulation
- 1.9.1. Advanced Therapies
- 1.9.2. Accelerated Approval
- 1.9.3. Biosimilars
- 1.9.4. Conditional Approval
- 1.9.5. Orphan Drugs

1.10. Dissemination of Research
- 1.10.1. Scientific Article
- 1.10.2. Types of Scientific Articles
- 1.10.3. Quality of Research *Checklist*
- 1.10.4. Drug Information Sources

Module 2. Clinical Trials I

2.1. Clinical Trials: Fundamental Concepts I
- 2.1.1. Introduction
- 2.1.2. Definition of clinical trial (CT)
- 2.1.3. History of Clinical Trials
- 2.1.4. Clinical Research
- 2.1.5. Parties Involved in CTs
- 2.1.6. Conclusions

2.2. Clinical Trials: Fundamental Concepts II
- 2.2.1. Standards of Good Clinical Practice
- 2.2.2. Clinical Trial Protocol and Annexes
- 2.2.3. Pharmacoeconomic Assessment
- 2.2.4. Aspects that Could Be Improved in Clinical Trials

2.3. Clinical Trials Classification
- 2.3.1. Clinical Trials Purpose
- 2.3.2. Clinical Trials According to the Scope of Research
- 2.3.3. Clinical Trials Methodology
- 2.3.4. Treatment Groups
- 2.3.5. Clinical Trials Masking
- 2.3.6. Treatment Assignment

2.4. Phase I Clinical Trials
- 2.4.1. Introduction
- 2.4.2. Phase I Clinical Trials Characteristics
- 2.4.3. Phase I Clinical Trials Design
  - 2.4.3.1. Single Dose Trials
  - 2.4.3.2. Multiple Dose Trials
  - 2.4.3.3. Pharmacodynamic Studies
  - 2.4.3.4. Pharmacokinetic Studies
  - 2.4.3.5. Bioavailability and Bioequivalence Studies
- 2.4.4. Phase I Units
- 2.4.5. Conclusions

2.5. Non-commercial Research
- 2.5.1. Introduction
- 2.5.2. Start-up of Non-Commercial Clinical Trials
- 2.5.3. Difficulties of the Independent Promoter
- 2.5.4. Promotion of Independent Clinical Research
- 2.5.5. Application for Grants for Non-commercial Clinical Research
- 2.5.6. Bibliography

2.6. Equivalence and Non-Inferiority EECC I
- 2.6.1. Equivalence and Non-Inferiority Clinical Trials
  - 2.6.1.1. Introduction
  - 2.6.1.2. Justification
  - 2.6.1.3. Therapeutic Equivalence and Bioequivalence
  - 2.6.1.4. Concept of Therapeutic Equivalence and Non-Inferiority
  - 2.6.1.5. Objectives
  - 2.6.1.6. Basic Statistical Aspects
  - 2.6.1.7. Intermediate Data Tracking
  - 2.6.1.8. Quality of Equivalence and Non-Inferiority RCTs
  - 2.6.1.9. Post-Equivalence
- 2.6.2. Conclusions

2.7. Equivalence and Non-Inferiority EECC II
- 2.7.1. Therapeutic Equivalence in Clinical Practice
  - 2.7.1.1. Level 1: Direct Trials Between 2 Drugs, with Equivalence or Non-Inferiority Design
  - 2.7.1.2. Level 2: Direct Trials Between 2 Drugs, with Statistically Significant Differences, but without Clinical Relevance
  - 2.7.1.3. Level 3: Not Statistically Significant Trials
  - 2.7.1.4. Level 4: Different Trials vs. a Third Common Denominator
  - 2.7.1.5. Level 5: Trials vs. Different Comparators and Observational Studies
  - 2.7.1.6. Supporting Documentation: Reviews, Clinical Practice Guidelines, Recommendations, Expert Opinion, Clinical Judgment
- 2.7.2. Conclusions

2.8. Guidelines for the Development of a Clinical Trial Protocol
- 2.8.1. Summary
- 2.8.2. Index
- 2.8.3. General Information
- 2.8.4. Justification
- 2.8.5. Hypothesis and Objectives of the Trial
- 2.8.6. Trial Design
- 2.8.7. Selection and Withdrawal of Subjects
- 2.8.8. Treatment of Subjects
- 2.8.9. Efficacy Assessment
- 2.8.10. Safety Assessment
  - 2.8.10.1. Adverse Events
  - 2.8.10.2. Adverse Events Management
  - 2.8.10.3. Adverse Events Notification
- 2.8.11. Statistics
- 2.8.12. Information and Consent
- 2.8.13. Conclusions

2.9. Non-Protocol Administrative Aspects of Clinical Trials
- 2.9.1. Documentation Required for the Start of the Trial
- 2.9.2. Subject Identification, Recruitment and Selection Records
- 2.9.3. Source Documents
- 2.9.4. Data Collection Notebooks (DCNs)
- 2.9.5. Monitoring
- 2.9.6. Conclusions

2.10. Data Collection Notebooks (DCNs)
- 2.10.1. Definition
- 2.10.2. Function
- 2.10.3. Importance and Confidentiality
- 2.10.4. Types of Data Collection Notebooks

2.10.5. Elaboration of the Data Collection Notebook
2.10.5.1. Types of Data
2.10.5.2. Order
2.10.5.3. Graphic Design
2.10.5.4. Filling in the Data
2.10.5.5. Recommendations
2.10.6. Conclusions

Module 3. Clinical Trials II

3.1. Involvement of the Pharmacy Service in the Realization of Clinical Trials Sample Management I
3.1.1. Manufacturing/Importation
3.1.2. Acquisition
3.1.3. Reception
3.1.3.1. Shipment Verification
3.1.3.2. Label Checking
3.1.3.3. Shipment Confirmation
3.1.3.4. Entry Registration
3.1.4. Custody/Storage
3.1.4.1. Expiration Control
3.1.4.2. Relabeling
3.1.4.3. Temperature Control
3.1.5. Sample Prescription Request
3.1.6. Medical Prescription Validation
3.1.7. Dispensing
3.1.7.1. Dispensing Procedure
3.1.7.2. Checking Storage Conditions and Expiration Date
3.1.7.3. Dispensing Act
3.1.7.4. Checkout
3.2. Involvement of the Pharmacy Service in the Realization of Clinical Trials Sample Management II
3.2.1. Preparation/Conditioning
3.2.1.1. Introduction
3.2.1.2. Exposure Routes and Handler Protection

3.2.1.3. Centralized Preparation Unit
3.2.1.4. Facilities
3.2.1.5. Individual Protection Equipment
3.2.1.6. Closed Systems and Handling Equipment
3.2.1.7. Technical Aspects of Preparation
3.2.1.8. Cleaning Standards
3.2.1.9. Waste Treatment in the Preparation Area
3.2.1.10. Actions in Case of Spill and/or Accidental Exposure
3.2.2. Accounting/Inventory
3.2.3. Return/Destruction
3.2.4. Reports and Statistics
3.3. Involvement of the Pharmacy Service in the Realization of Clinical Trials Role of the Pharmacist
3.3.1. Visits Manager
3.3.1.1. Preselection Visit
3.3.1.2. Initiation Visit
3.3.1.3. Monitoring Visit
3.3.1.4. Audits and Inspections
3.3.1.5. Closing Visit
3.3.1.6. Archive
3.3.2. Member of the Ethics Committee
3.3.3. Clinical-Research Activity
3.3.4. Teaching Activity
3.3.5. Process Auditor
3.3.6. Complexity of CTs
3.3.7. CTs as Sustainability the Health Care System
3.4. Clinical Trials in the Hospital Urology Service I
3.4.1. Basic Principles of Urologic Pathology Related to Clinical Trials
3.4.1.1. Non-Oncologic Urologic Pathology
3.4.1.1.1. Benign Prostatic Hypertrophy
3.4.1.1.2. Urinary Infection
3.4.1.1.3. Erectile Dysfunction
3.4.1.1.4. Hypogonadism
3.4.1.2. Oncologic Urologic Pathology
3.4.1.2.1. Bladder Tumors
3.4.1.2.2. Prostate Cancer
3.4.2. Background and Rationale for Clinical Trials in Urology
3.4.2.1. Foundation
3.4.2.2. Background
3.4.2.3. Placebo Rationale
3.4.2.4. Name and Mechanism of Action of the Investigational Product
3.4.2.5. Conclusions from Previous Studies in Humans
3.4.2.6. Benefits and Risks of Study Medication
3.4.2.6.1. Dosage and Administration
3.4.2.6.2. Medication Management Guidelines at Home
3.4.2.6.3. Overdosage/Infradosification
3.4.2.7. Double-Blind/Open Study
3.4.3. Objectives and Assessment Criteria of the Study
3.4.3.1. Study Objectives
3.4.3.1.1. Safety Objective
3.4.3.1.2. Exploratory Objectives
3.4.3.2. Assessment Criteria of the Study
3.4.3.2.1. Main Efficacy Assessment Criteria
3.4.3.2.2. Secondary Efficacy Assessment Criteria
3.4.4. Research Plan
3.4.5. Preselection of Candidates for Clinical Trials
3.4.6. Study Procedures by Period
3.5. Clinical Trials in the Urology Service II
3.5.1. Patient Retention
3.5.1.1. Post-Treatment Monitoring Visits
3.5.1.2. Long-Term Monitoring Visits
3.5.2. Safety Assessments
3.5.2.1. Adverse Effects Management
3.5.2.2. SAEs Management
3.5.2.3. Assigned Treatment Emergency Unblinding

3.5.3. Study Administration
3.5.3.1. Dose-Limiting Toxicities
3.5.3.2. Interrupting the Treatment
3.5.5. Quality Control and Compliance
3.5.5.1. Authorization of Subjects Protected Health Information
3.5.5.2. Retention of Study Records and Files
3.5.5.3. Data Collection Notebooks
3.5.5.4. Protocol Amendments
3.5.6. Conclusions
3.6. Approval of a Clinical Trial to the Urology Service Steps to Follow Trial Conclusion
3.6.1. Feasibility
3.6.2. Preselection Visit
3.6.2.1. Main Investigators Role
3.6.2.2. Logistics and Hospital Resources
3.6.3. Documentation
3.6.4. Initiation Visit
3.6.5. Source Document
3.6.5.1. Patient's Clinical History
3.6.5.2. Hospital Reports
3.6.6. Vendors
3.6.6.1. Interactive Web Response Systems (IWRS)
3.6.6.2. Electronic Case Report Form (eCRF)
3.6.6.3. Images
3.6.6.4. Suspected Unexpected Serious Adverse Reactions (SUSARs)
3.6.6.5. Accounting
3.6.7. Training
3.6.8. Delegation of Functions
3.6.9. Visit to Other Services Involved
3.6.10. Closing the Trial
3.7. General Information about Clinical Trials in Children and Adolescents
3.7.1. History of Clinical Trials in Children
3.7.2. Informed Consent
3.8. Clinical Trials in Adolescents
3.8.1. Adolescent Clinical Trials Practical Features
3.8.2. New Approaches to Adolescent Trials
3.9. Clinical Trials in Children
3.9.1. Specific Physiological Characteristics of the Child
3.9.2. Children Clinical Trials
3.10. Clinical Trials in Neonatal
3.10.1. Specific Physiological Characteristics the Neonatal
3.10.2. Neonatal Clinical Trials

Module 4. Monitoring of Clinical Trials I

4.1. Promoter I
4.1.1. General Aspects
4.1.2. Promoter Responsibilities
4.2. Promoter II
4.2.1. Project Management
4.2.2. Non-commercial Research
4.3. Protocol
4.3.1. Definition and Content
4.3.2. Protocol Compliance
4.4. Monitoring
4.4.1. Introduction
4.4.2. Definition
4.4.3. Monitoring Objectives
4.4.4. Types of Monitoring: Traditional and Risk-Based
4.5. Clinical Trial Monitor I
4.5.1. Who can be a Monitor?
4.5.2. CRO: Clinical Research Organization
4.5.3. Monitoring Plan

4.6. The Monitor II
- 4.6.1. Monitors Responsibilities
- 4.6.2. Verification of Source Documents Source Documents Verification (SDV)
- 4.6.3. Monitors Report and Monitoring Letter

4.7. Selection Visit
- 4.7.1. Researcher Selection
- 4.7.2. Aspects to Take into Account
- 4.7.3. Suitability of Facilities
- 4.7.4. Visit to other Hospital Services
- 4.7.5. Deficiencies in Study Facilities and Staffing

4.8. Start Up in a Clinical Research Center
- 4.8.1. Definition and Functionality
- 4.8.2. Essential Documents at the Beginning of the Trial

4.9. Initiation Visit
- 4.9.1. Objective
- 4.9.2. Preparing the Initiation Visit
- 4.9.3. Investigators File
- 4.9.4. Investigator Meeting

4.10. Initial Visit in Hospital Pharmacy
- 4.10.1. Objective
- 4.10.2. Investigational Drug Management
- 4.10.3. Temperature Control
- 4.10.4. General Deviation Procedure

Module 5. Monitoring of Clinical Trials II

5.1. Follow-Up Visit
- 5.1.1. Preparation
  - 5.1.1.1. Letter Confirming the Visit
  - 5.1.1.2. Preparation
- 5.1.2. Center Development
  - 5.1.2.1. Documentation Review
  - 5.1.2.2. SAE
  - 5.1.2.3. Inclusion and Exclusion Criteria
  - 5.1.2.4. Collate
- 5.1.3. Research Team Training
  - 5.1.3.1. Monitoring
    - 5.1.3.1.1. Monitoring Report Preparation
    - 5.1.3.1.2. Issue Tracking
    - 5.1.3.1.3. Team Support
    - 5.1.3.1.4. Monitoring Letter
  - 5.1.3.2. Temperature
    - 5.1.3.2.1. Adequate Medication
    - 5.1.3.2.2. Reception
    - 5.1.3.2.3. Expiration
    - 5.1.3.2.4. Dispensing
    - 5.1.3.2.5. Setting Up
    - 5.1.3.2.6. Return
    - 5.1.3.2.7. Storage
    - 5.1.3.2.8. Documentation
  - 5.1.3.3. Samples
    - 5.1.3.3.1. Local and Central
    - 5.1.3.3.2. Types
    - 5.1.3.3.3. Temperature Registration
    - 5.1.3.3.4. Calibration/Maintenance Certificate

5.1.3.4. Meeting with the Research Team
5.1.3.4.1. Signature of Pending Documentation
5.1.3.4.2. Discussion of Findings
5.1.3.4.3. Re-Training
5.1.3.4.4. Corrective Actions
5.1.3.5. Review of ISF (Investigator Site File)
5.1.3.5.1. Clinical Investigations (CIs) and Protocols
5.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS
5.1.3.5.3. LOGs
5.1.3.5.4. Site Visit Letter
5.1.3.5.5. New Documentation
5.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)
5.1.3.6.1. Concept
5.1.3.3.2. Principal Investigator Review
5.1.3.7. Electronic Notebook

5.2. Close-Out Visit
5.2.1. Definition
5.2.2. Reasons for Close-Out Visits
5.2.2.1. Completion of the Clinical Trial
5.2.2.2. Not Complying with Protocol
5.2.2.3. Not Complying with Good Clinical Practices
5.2.2.4. At the Investigators Request
5.2.2.5. Low Recruitment
5.2.3. Procedures and Responsibilities
5.2.3.1. Before the Close-Out Visit
5.2.3.2. During the Close-Out Visit
5.2.3.3. After the Close-Out Visit
5.2.4. Pharmacy Close-Out Visit
5.2.5. Final Report
5.2.6. Conclusions

5.3. Queries Management, Database Slicing
5.3.1. Definition
5.3.2. Queries Rules
5.3.3. How are Queries Generated?
5.3.3.1. Automatically
5.3.3.2. By the Monitor
5.3.3.3. By an External Reviewer
5.3.4. When are Queries Generated?
5.3.4.1. After a Monitoring Visit
5.3.4.2. Close to Closing a Database
5.3.5. Query Status
5.3.5.1. Open
5.3.5.2. Pending Revision
5.3.5.3. Closed
5.3.6. Database Slicing
5.3.6.1. Most Frequent Database Slicing Errors
5.3.7. Conclusions

5.4. AE Management and SAE Notification
5.4.1. Definitions
5.4.1.1. Adverse Events Adverse Event (AE)
5.4.1.2. Adverse Reactions (AR)
5.4.1.3. Serious Adverse Event(SAE) or Serious Adverse Reaction (SAR)
5.4.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR)
5.4.2. Data to be Collected by the Researcher
5.4.3. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
5.4.3.1. Description
5.4.3.2. Dates
5.4.3.3. Unraveling
5.4.3.4. Intensity
5.4.3.5. Actions Taken
5.4.3.6. Causal Relationship
5.4.3.7. Basic Questions
5.4.3.7.1. Who Notifies, What is Notified, Who is Notified, How are they Notified, When are they Notified?

5.4.4. Procedures for the Communication of AE/AR with Investigational Drugs
5.4.4.1. Expedited Notification of Individual Cases
5.4.4.2. Periodic Security Reports
5.4.4.3. Ad Hoc Safety Reports
5.4.4.4. Annual Reports
5.4.5. Special Interest Events
5.4.6. Conclusions

5.5. Clinical Research Associate (CRA) Standard Operating Procedures Standard Operating Procedures (SOP)
5.5.1. Definition and objectives
5.5.2. Writing a SOP
5.5.2.1. Procedure
5.5.2.2. Format
5.5.2.3. Implementation
5.5.2.4. Review
5.5.3. SOP Feasibility and Site Qualification Visit
5.5.3.1. Procedures
5.5.4. SOP Initiation Visit
5.5.4.1. Procedures Prior to the Initiation Visit
5.5.4.2. Procedures During the Initiation Visit
5.5.4.3. Monitoring Initiation Visit Procedures
5.5.5. SOP Monitoring Visit
5.5.5.1. Procedures Prior to the Monitoring Visit
5.5.5.2. Procedures During the Monitoring Visit
5.5.5.3. Monitoring Letter
5.5.6. SOP for Closing Visit
5.5.6.1. Preparing the Close-Out Visit
5.5.6.2. Manage the Close-Out Visit
5.5.6.3. Monitoring After a Close-Up Visit
5.5.7. Conclusions

5.6. Quality Guarantee Audits and Inspections
- 5.6.1. Definition
- 5.6.2. Types of Audits
  - 5.6.2.1. Internal Audits
  - 5.6.2.2. External Audits or Inspections
- 5.6.3. How Prepare an Audit
- 5.6.4. Principal Findings
- 5.6.5. Conclusions

5.7. Protocol Deviations
- 5.7.1. Criteria
  - 5.7.1.1. Non-Compliance with Inclusion Criteria
  - 5.7.1.2. Compliance with Exclusion Criteria
- 5.7.2. International Classification of Functioning (ICF) Deficiencies
  - 5.7.2.1. Correct Signatures on Documents (CI, LOG)
  - 5.7.2.2. Correct Dates
  - 5.7.2.3. Correct Documentation
  - 5.7.2.4. Correct Storage
  - 5.7.2.5. Correct Version
- 5.7.3. Out-Of-Window Visits
- 5.7.4. Poor or Wrong Documentation
- 5.7.5. The 5 Rights
  - 5.7.5.1. Right Patient
  - 5.7.5.2. Right Drug
  - 5.7.5.3. Right Time
  - 5.7.5.4. Right Dose
  - 5.7.5.5. Right Route
- 5.7.6. Missing Samples and Parameters
  - 5.7.6.1. Missing Samples
  - 5.7.6.2. Parameter Not Performed
  - 5.7.6.3. Sample Not Sent On Time
  - 5.7.6.4. Time of Sample Collection
  - 5.7.6.6. Request for Kits Out of Time

5.7.7. Information Privacy
5.7.7.1. Information Security
5.7.7.2. Reporting Security
5.7.7.3. Photo Security
5.7.8. Temperature Deviations
5.7.8.1. Register
5.7.8.2. Inform
5.7.8.3. Act
5.7.9. Open Blinding at the Wrong Time
5.7.10. PI Availability
5.7.10.1. Not Updated in Interactive Voice Response Services (IVRS)
5.7.10.2. Not Sent on Time
5.7.10.3. Not Registered on Time
5.7.10.4. Broken Stock
5.7.11. Forbidden Medication
5.7.12. Key and Non-Key
5.8. Source and Essential Documents
5.8.1. Features
5.8.2. Source Documents Location
5.8.3. Source Document Access
5.8.4. Source Document Types
5.8.5. How to Correct a Source Document
5.8.6. Source Document Retention Time
5.8.7. Main Components of the Medical History
5.8.8. Investigator's Brochure (IB)
5.9. Monitoring Plan
5.9.1. Visits
5.9.2. Frequency (F)
5.9.3. Organisation
5.9.4. Confirmation
5.9.5. Site Issues Categorization
5.9.6. Communication with Researchers
5.9.7. Research Team Training
5.9.8. Trial Master File
5.9.9. Reference Documents
5.9.10. Electronic Notebooks Remote Review
5.9.11. Data Privacy
5.9.12. Center Management Activities
5.10. Data Collection Notebooks
5.10.1. Concept and History
5.10.2. Timeline Compliance
5.10.3. Data Validation
5.10.4. Management of Data Inconsistencies or Queries
5.10.5. Data Exports
5.10.6. Security and Roles
5.10.7. Traceability and Logs
5.10.8. Report Generation
5.10.9. Notifications and Alerts
5.10.10. Electronic Notebook Vs. Paper Notebook

Module 6. Coordination of Clinical Trials I

6.1. The Researcher's File – General Aspects
6.1.1. What is the Researcher's File? What type of Documentation Should It Contain and Why? How Long Should the Information be Stored?
6.1.2. Contract
6.1.2.1. Original Copies
6.1.2.2. Amendments
6.1.3. Ethical Committees
6.1.3.1. Approvals
6.1.3.2. Amendments

6.1.4. Regulatory Authorities
6.1.4.1. Approvals
6.1.4.2. Modifications
6.1.4.3. Monitoring and Final Reports
6.1.5. Civil Liability Insurance
6.2. Documentation Associated with the Research Team
6.2.1. CV
6.2.2. Good Clinical Practice Certificate
6.2.3. Specific Training Certificates
6.2.4. Signed Statement of the Investigator, Financial Disclosure
6.2.5. Task Delegation
6.3. Study Protocol and Monitoring
6.3.1. Protocol Versions, Summary and Pocket Guides
6.3.2. Protocol
6.3.3. Protocol Amendments
6.3.4. Protocol Signature Form
6.4. Patient Related Material
6.4.1. Patient Information Form and Informed Consent Form (Copies and Specimens for Signature)
6.4.2. Modifications to the Consent (Copies and Specimens for Signature)
6.4.3. Study Participation Cards
6.4.4. Information for Primary Care Physicians
6.4.5. Questionnaires
6.5. Patient Forms, Monitoring Visits
6.5.1. Patient (Screening) Form
6.5.2. Patient Recruitment and Identification Form
6.5.3. Visit Logs and Reports Form
6.6. Data Collection Notebooks (DCNs)
6.6.1. Types
6.6.2. Guide or Manual for Data Entry in the DCN
6.6.3. Copy of DCN
6.7. Investigator's Brochure (Studies with Medical Devices) or Fact Sheet (Clinical Trials with Medication)
6.7.1. Investigators Brochure (IB)
6.7.2. Technical Data Sheets of the Drugs Under Study (If Marketed)
6.7.3. Instructions for the Control of Specific Parameters (Example)
6.7.4. Instructions for Return of Medication or Medical Devices
6.8. Material Related to Laboratory and Specific Procedures
6.8.1. Central Laboratories and Sample Shipping Documents
6.8.2. Local Laboratory: Qualification Certificates and Ranks
6.8.3. Instructions for Acquiring and/or Processing Medical Images
6.8.4. Sample and Material Shipment
6.9. Security/Safety
6.9.1. Adverse Events and Serious Adverse Events
6.9.2. Notification Instructions
6.9.3. Relevant Security Correspondence
6.10. Others
6.10.1. Contact Information
6.10.2. Note to File
6.10.3. Correspondence with the Promoter
6.10.4. Acknowledgements of Receipt
6.10.5. Newsletter

Module 7. Coordination of Clinical Trials II

7.1. Research Team
7.1.1. Components of a Research Team
7.1.1.1. Principal Investigator
7.1.1.2. Sub-Investigator
7.1.1.3. Coordinator
7.1.1.4. Rest of the Team
7.1.2. Responsibilities of the Research Team
7.1.2.1. Compliance with Good Clinical Practices and Current Legislation
7.1.2.2. Compliance of the Study Protocol
7.1.2.3. Care and Maintenance of the Research Archive

7.1.3. Task Delegation
7.1.3.1. Document Details
7.1.3.2. Example
7.2. Trial Coordinator
7.2.1. Responsibilities
7.2.1.1. Primary Responsibilities
7.2.1.2. Secondary Responsibilities
7.2.2. Capabilities and Competencies
7.2.2.1. Academic Background
7.2.2.2. Skills
7.2.3. Clinical Trials vs. Observational Study
7.2.3.1. Types of Clinical Trials
7.2.3.2. Types of Observational Studies
7.3. Protocol
7.3.1. Primary and Secondary Objectives
7.3.1.1. What Are They and Who Defines Them?
7.3.1.2. Importance During the Course of the Clinical Trial
7.3.2. Inclusion and Exclusion Criteria
7.3.2.1. Inclusion Criteria
7.3.2.2. Exclusion Criteria
7.3.2.3. Example
7.3.3. Flowchart
7.3.3.1. Document and Explanation
7.3.4. Concomitant Medication and Prohibited Medication
7.3.4.1. Concomitant Drug
7.3.4.2. Forbidden Medication
7.3.4.3. Washout Periods
7.4. Documentation Required to Initiate Clinical Trial
7.4.1. Curriculum of the Research Team
7.4.1.1. Basic Notions of a Research Curriculum
7.4.1.2. Good Clinical Practice Example
7.4.2. Good Clinical Practice
7.4.2.1. Origin of Good Clinical Practices
7.4.2.2. How to Get Certified?
7.4.2.3. Expiration
7.4.3. Suitability of the Research Team
7.4.3.1. Who Signs the Document?
7.4.3.2. Presentation to Ethics Committee
7.4.4. Suitability of Facilities
7.4.4.1. Who Signs the Document?
7.4.4.2. Ethical Committee Presentation
7.4.5. Calibration Certificates
7.4.5.1. Calibration
7.4.5.2. Calibration Equipment
7.4.5.3. Valid Certifications
7.4.5.4. Expiration
7.4.6. Other Training
7.4.6.1. Necessary Certifications According Protocol
7.5. Main Functions Trial Coordinator
7.5.1. Documentation Preparation
7.5.1.1. Documentation Requested for Approval of the Study at the Center
7.5.2. Investigator Meeting
7.5.2.1. Importance
7.5.2.2. Attendees
7.5.3. Initiation Visit
7.5.3.1. Duties of the Coordinator
7.5.3.2. Functions of the Principal Investigator and Sub-Investigators
7.5.3.3. Promoter
7.5.3.4. Monitor
7.5.4. Monitoring Visit
7.5.4.1. Preparation After a Monitoring Visit
7.5.4.2. Functions During the Monitoring Visit
7.5.5. End-Of-Study Visit
7.5.5.1. Storage of the Researchers File

7.6. Relationship with the Patient
- 7.6.1. Preparation of Visits
  - 7.6.1.1. Consents and Amendments
  - 7.6.1.2. Visit Window
  - 7.6.1.3. Identify the Responsibilities of the Investigation Team during the Visit
  - 7.6.1.4. Visit Calculator
  - 7.6.1.5. Preparation of Documentation to be Used During the Visit
- 7.6.2. Complementary Tests
  - 7.6.2.1. Analysis
  - 7.6.2.2. Chest X-Ray
  - 7.6.2.3. Electrocardiogram
- 7.6.3. Calendar of Visits
  - 7.6.3.1. Example

7.7. Samples
- 7.7.1. Equipment and Materials Necessary
  - 7.7.1.1. Centrifuge
  - 7.7.1.2. Incubator
  - 7.7.1.3. Refrigerators
- 7.7.2. Processing of Samples
  - 7.7.2.1. General Procedure
  - 7.7.2.2. Example
- 7.7.3. Laboratory Kits
  - 7.7.3.1. What are they?
  - 7.7.3.2. Expiration
- 7.7.4. Shipment of Samples
  - 7.7.4.1. Sample Storage
  - 7.7.4.2. Ambient Temperature Shipment
  - 7.7.4.3. Shipping Frozen Samples

7.8. Data Collection Notebooks
- 7.8.1. What Is It?
  - 7.8.1.1. Types of Notebooks
  - 7.8.1.2. Paper Notebook
  - 7.8.1.3. Electronic Notebook
  - 7.8.1.4. Specific Notebooks According to Protocol
- 7.8.2. How To Complete It?
  - 7.8.2.1. Example
- 7.8.3. Query
  - 7.8.3.1. What Is a Query?
  - 7.8.3.2. Resolution Time
  - 7.8.3.3. Who Can Open a Query?

7.9. Randomization Systems
- 7.9.1. What Is It?
- 7.9.2. Types of IWRS:
  - 7.9.2.1. Telephonics
  - 7.9.2.2. Electronics
- 7.9.3. Responsibilities Researcher Vs. Research Team
  - 7.9.3.1. Screening
  - 7.9.3.2. Randomization
  - 7.9.3.3. Scheduled Visits
  - 7.9.3.4. Unscheduled Visits
  - 7.9.3.5. Blinding Opening
- 7.9.4. Medication
  - 7.9.4.1. Who Receives the Medication?
  - 7.9.4.2. Drug Traceability
- 7.9.5. Return of Medication
  - 7.9.5.1. Functions of the Research Team in the Return of Medication

7.10. Biological Treatments
- 7.10.1. Coordination of Clinical Trials with Biologics
  - 7.10.1.1. Biological Treatments
  - 7.10.1.2. Types of Treatment
- 7.10.2. Types of Studies
  - 7.10.2.1. Biological Criteria Placebo
  - 7.10.2.2. Biological Criteria Biological Criteria
- 7.10.3. Biological Management
  - 7.10.3.1. Administration
  - 7.10.3.2. Traceability

7.10.4. Rheumatic Diseases
7.10.4.1. Rheumatoid Arthritis
7.10.4.2. Psoriatic Arthritis
7.10.4.3. Lupus
7.10.4.4. Scleroderma

Module 8. Follow-up of Patients in Clinical Trials

8.1. Patient Care in Outpatient Clinics
8.1.1. Visits in the Protocol
8.1.1.1. Visits and Procedures
8.1.1.2. Window of Realization of the Different Visits
8.1.1.3. Database Considerations
8.2. Materials Used in the Different Study Visits
8.2.1. Questionnaires
8.2.2. Drug Adherence Cards
8.2.3. Symptom Cards
8.2.4. Study Card
8.2.5. Electronic Devices
8.2.6. Suicide Risk Scales
8.2.7. Material for the Displacement of Patients
8.2.8. Others
8.3. Strategies for Patient Retention:
8.3.1. Possible Causes for Abandonment of a Clinical Trial
8.3.2. Strategies and Solutions to the Possible Causes of Abandonment
8.3.3. Long-Term Monitoring of Patients Leaving the Study Prematurely
8.4. Loss of Patient Follow-Up:
8.4.1. Definition of Loss of Monitoring
8.4.2. Causes of Loss of Monitoring
8.4.3. Resumption of Monitoring
8.4.3.1. Re-Inclusion Back into the Protocol
8.5. Adherence to Pharmacological Treatment under Study
8.5.1. Calculation of Adherence to Pharmacological Treatment
8.5.2. Risk Factors for Therapeutic Non-Compliance
8.5.3. Strategies to Strengthen Adherence to Treatment
8.5.4. Treatment Dropout
8.5.5. Study Drug Interactions
8.6. Follow-Up of Adverse Reactions, and Symptom Management in the Study Medication Intake
8.6.1. Study Medication
8.6.1.1. Different Drug Presentations
8.6.1.2. Procedure and Preparation of Study Medication
8.6.2. Drug-Related Adverse Reactions
8.6.3. Non-Drug Related Adverse Reactions
8.6.4. Adverse Reaction Treatment
8.7. Monitoring of Patient Attendance at Study Visits
8.7.1. Visit Calculator
8.7.2. Study Visits Control
8.7.3. Tools for Compliance and Visitor Control
8.8. Difficulties in Patient Monitoring Within a Clinical Trial
8.8.1. Problems Related to Adverse Patient Events
8.8.2. Problems Related to the Patients Work Situation
8.8.3. Problems Related to the Patients Residence
8.8.4. Problems Related to the Patients Legal Status
8.8.5. Solutions and their Treatments
8.9. Monitoring of Patients in Treatment with Psychopharmaceuticals
8.10. Monitoring of Patients During Hospitalization

Module 9. Biostatistics

9.1. Study Design
9.1.1. Research Question
9.1.2. Population to Analyze
9.1.3. Classification
9.1.3.1. Comparison between Groups
9.1.3.2. Maintenance of the Described Conditions
9.1.3.3. Assignment to Treatment Group
9.1.3.4. Degree of Masking
9.1.3.5. Modality of Intervention
9.1.3.6. Centers Involved

9.2. Types of Randomized Clinical Trials: Validity and Biases
- 9.2.1. Types of Clinical Trials
  - 9.2.1.1. Superiority Study
  - 9.2.1.2. Equivalence or Bioequivalence Study
  - 9.2.1.3. Non-Inferiority Study
- 9.2.2. Analysis and Validity of Results
  - 9.2.2.1. Internal Validity
  - 9.2.2.2. External Validity
- 9.2.3. Biases
  - 9.2.3.1. Selection
  - 9.2.3.2. Measurement
  - 9.2.3.3. Confusion

9.3. Sample Size Protocol Deviations
- 9.3.1. Parameters Used
- 9.3.2. Protocol Justification
- 9.3.3. Protocol Deviations

9.4. Methodology
- 9.4.1. Missing Data Handling
- 9.4.2. Statistical Methods
  - 9.4.2.1. Description of Data
  - 9.4.2.2. Survival
  - 9.4.2.3. Logistic Regression
  - 9.4.2.4. Mixed Models
  - 9.4.2.5. Sensitivity Analysis
  - 9.4.2.6. Multiplicity Analysis

9.5. When Does the Statistician Become Part of the Project
- 9.5.1. Statistician Role
- 9.5.2. Points of the Protocol to be Reviewed and Described by the Statistician
  - 9.5.2.1. Study Design
  - 9.5.2.2. The Primary and Secondary Objectives of the Study
  - 9.5.2.3. Sample Size Calculation
  - 9.5.2.4. Variables
  - 9.5.2.5. Statistical Justification
  - 9.5.2.6. Material and Methods used to Study the Objectives of the Study

9.6. CRD Design
- 9.6.1. Information Gathering Variables Dictionary
- 9.6.2. Variables and Data Entry
- 9.6.3. Database Security, Testing and Debugging

9.7. Statistical Analysis Plan
- 9.7.1. What is a Statistical Analysis Plan?
- 9.7.2. When to Perform the Statistical Analysis Plan
- 9.7.3. Statistical Analysis Plan Parts

9.8. Intermediate Analysis
- 9.8.1. Reasons for an Early Stopping of a Clinical Trial
- 9.8.2. Implications of Early Termination of a Clinical Trial
- 9.8.3. Statistical Designs

9.9. Final Analysis
- 9.9.1. Final Report Criteria
- 9.9.2. Plan Deviations
- 9.9.3. Guidelines for the Elaboration of the Final Report of a Clinical Trial

9.10. Statistical Review of a Protocol
- 9.10.1. Checklist
- 9.10.2. Frequent Errors in the Review of a Protocol

A unique education opportunity to advance your career"

06

Methodology

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

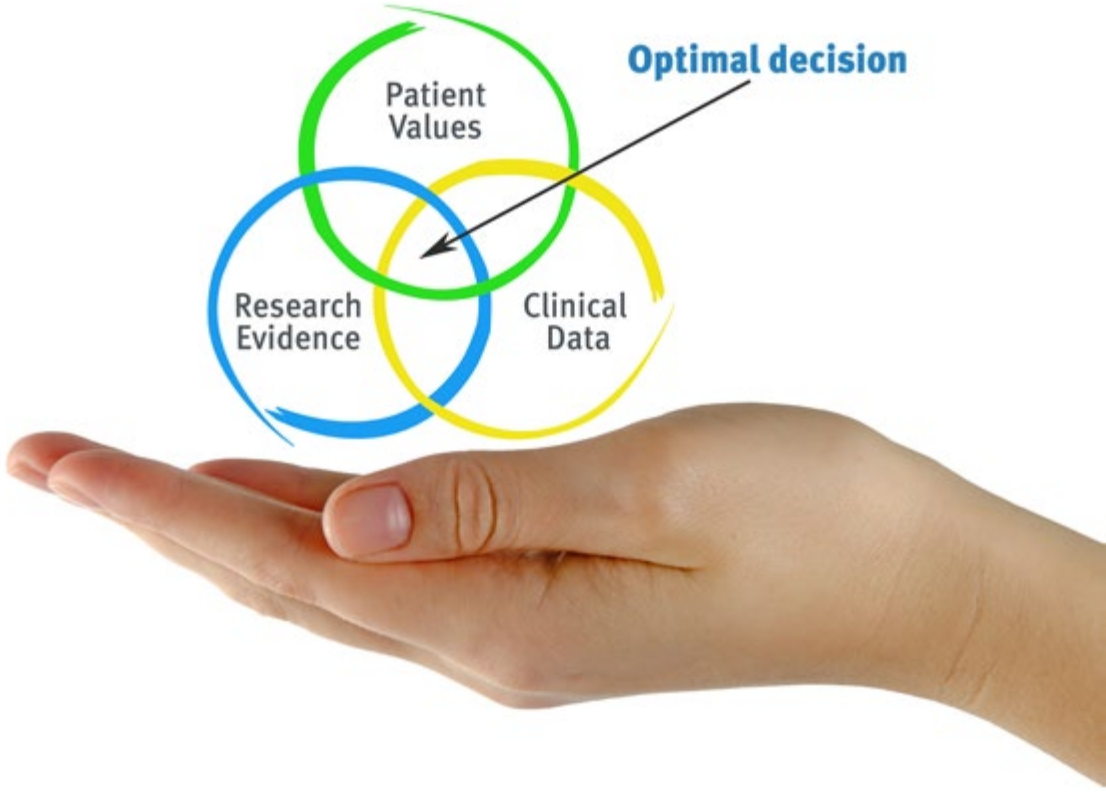
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

Discover Relearning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"

At TECH Nursing School we use the Case Method

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

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



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

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

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

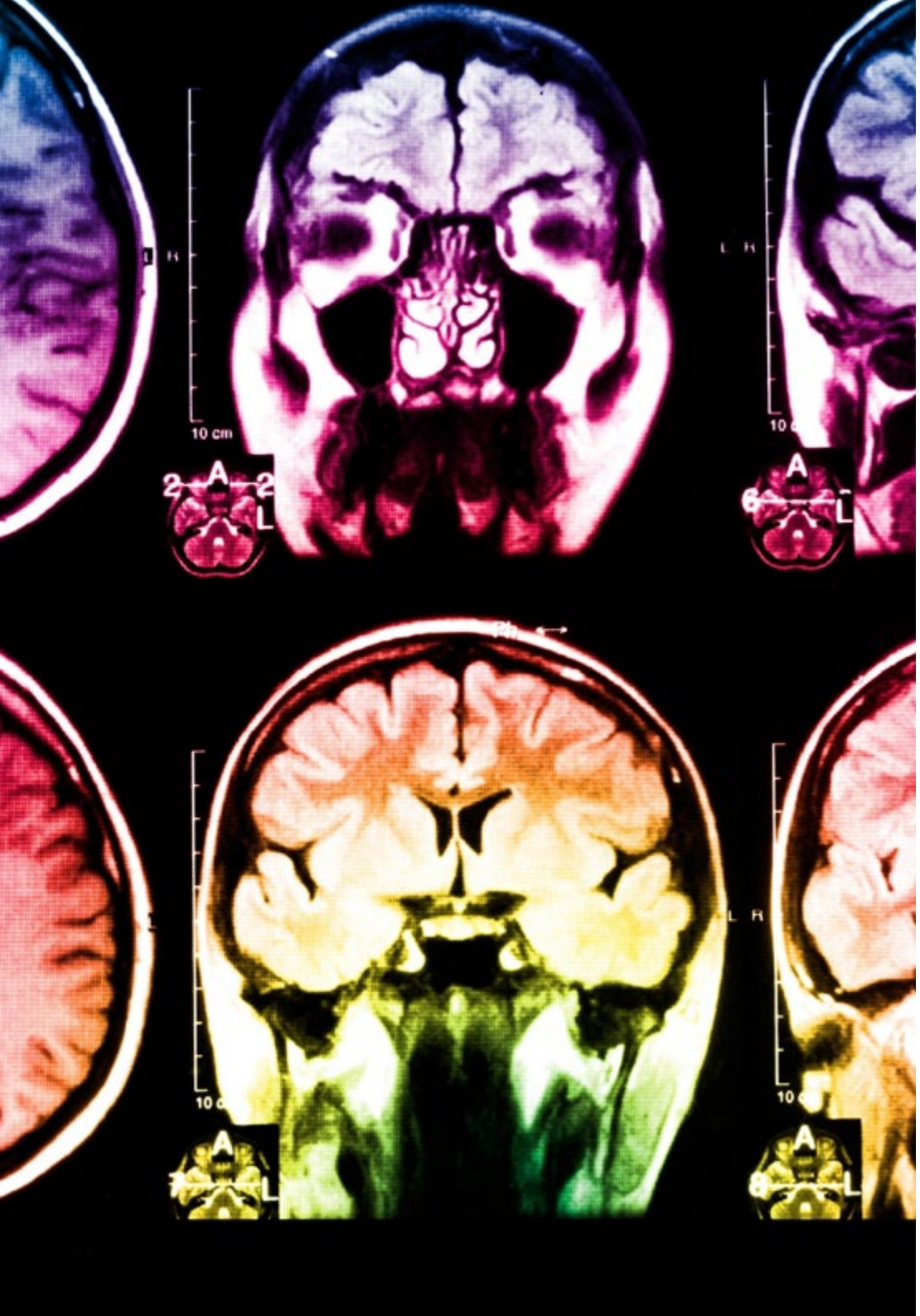
1. Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into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

Relearning Methodology

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

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

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



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

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

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

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

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

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

Study Material

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

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

Nursing Techniques and Procedures on Video

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

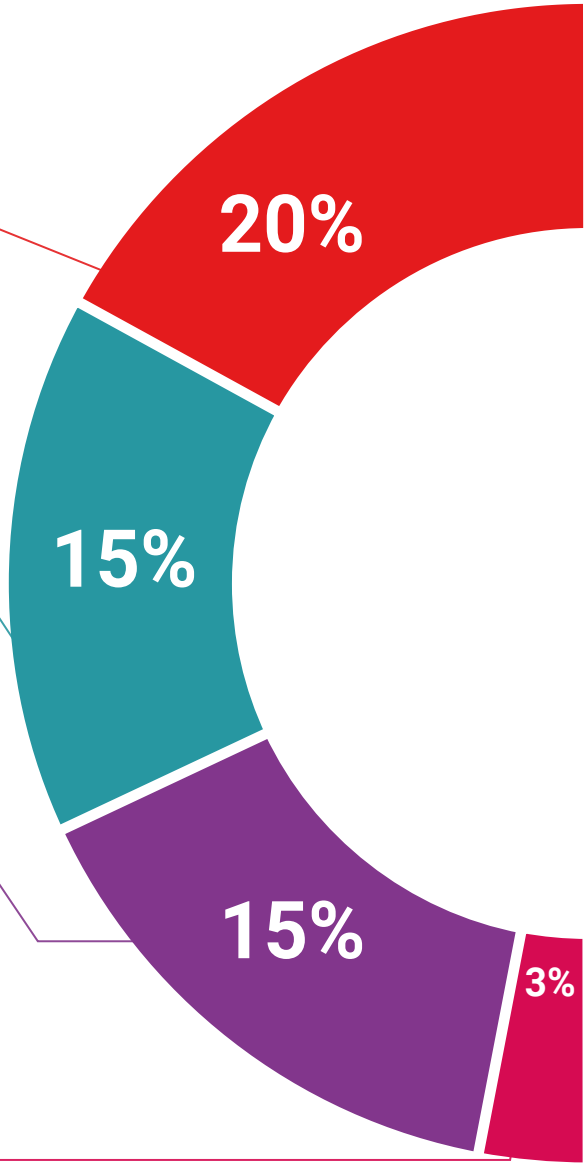
Interactive Summaries

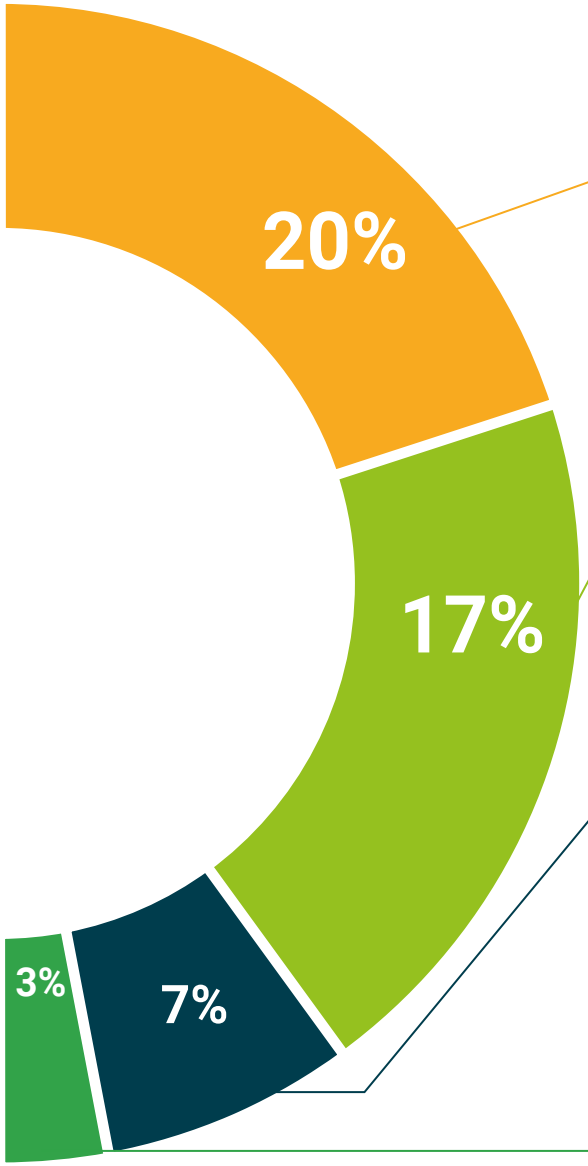
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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

Additional Reading

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





Expert-Led Case Studies and Case Analysis

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

Testing & Retesting

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

Classes

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

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

Quick Action Guides

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

07

Certificate

The Professional Master's Degree in Clinical Trials for Nursing Monitoring guarantees you, in addition to the most rigorous and up-to-date training, access to a Professional Master's Degree issued by TECH Technological University.

Successfully complete this program and receive your university degree without travel or laborious paperwork”

This **Professional Master's Degree in Management and Monitoring of Clinical Trials for Nursing** contains the most complete and up-to-date scientific program on the market.

After the student has passed the assessments, they will receive their corresponding **Professional Master's Degree** issued by **TECH Technological University** via tracked delivery*.

The diploma issued by **TECH Technological University** will reflect the qualification obtained in the Professional Master's Degree, and meets the requirements commonly demanded by labor exchanges, competitive examinations, and professional career evaluation committees.

Title: **Professional Master's Degree in Management and Monitoring of Clinical Trials for Nursing**

Official Nº of hours: **1,500 h.**


tech technological university

Awards the following

DIPLOMA

to

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

For having successfully passed and accredited the following program

PROFESSIONAL MASTER'S DEGREE

in

Management and Monitoring of Clinical Trials for Nursing

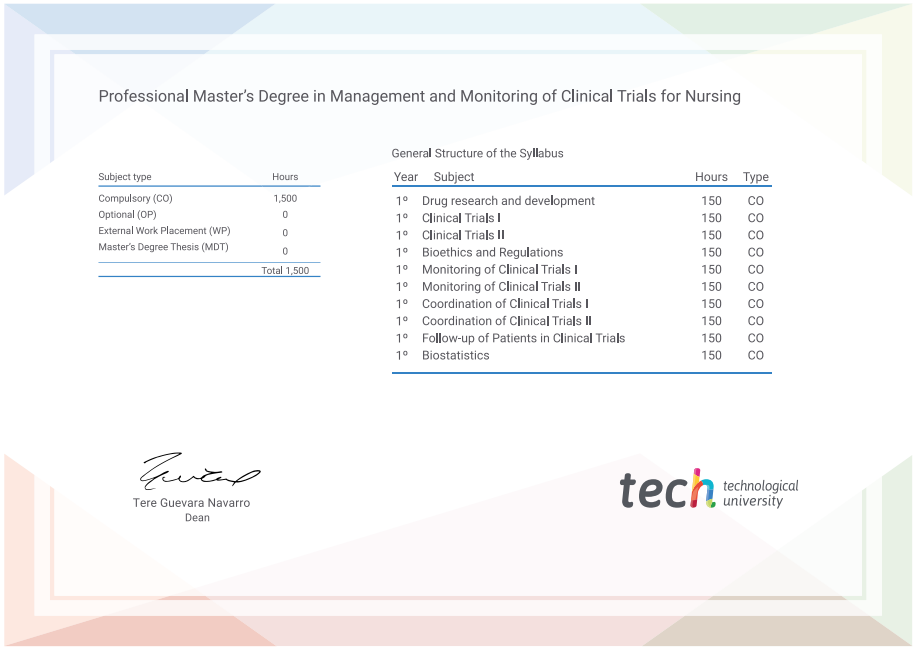
This is a qualification awarded by this University, equivalent to 1,500 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

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


Professional Master's Degree in Management and Monitoring of Clinical Trials for Nursing

Subject type	Hours
Compulsory (CO)	1,500
Optional (OP)	0
External Work Placement (WP)	0
Master's Degree Thesis (MDT)	0
	Total 1,500

General Structure of the Syllabus

Year	Subject	Hours	Type
1º	Drug research and development	150	CO
1º	Clinical Trials I	150	CO
1º	Clinical Trials II	150	CO
1º	Bioethics and Regulations	150	CO
1º	Monitoring of Clinical Trials I	150	CO
1º	Monitoring of Clinical Trials II	150	CO
1º	Coordination of Clinical Trials I	150	CO
1º	Coordination of Clinical Trials II	150	CO
1º	Follow-up of Patients in Clinical Trials	150	CO
1º	Biostatistics	150	CO

Tere Guevara Navarro
Dean

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

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Professional Master's Degree

Management and Monitoring of Clinical Trials for Nursing

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

Professional Master's Degree

Management and Monitoring of Clinical Trials for Nursing

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