Professional Master's Degree

MBA in Clinical Trials Management and Monitoring for Nursing

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Professional Master's Degree

MBA in Clinical Trials Management and Monitoring for Nursing

- Modality: **online**
- Duration: **12 months**
- Certificate: **TECH Global University**
- Accreditation: **90 ECTS**
- Schedule: **at your own pace**
- Exams: **online**

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

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01

Introduction to the Program

The Management and Monitoring of Clinical Trials for Nursing is a fundamental pillar in the development of new treatments and the improvement of healthcare. So much so that, according to the Association for Precision Medicine, more than 70% of medical decisions are based on data obtained through rigorous clinical studies. In a scenario where therapeutic innovation and patient safety are central, nursing professionals play an essential role in the supervision and management of these processes. In response to this reality, TECH presents a university program structured to strengthen strategic competencies and optimize the management of clinical trials.

With this 100% online MBA, you will efficiently manage the resources of Clinical Trials in Nursing, optimizing their precision and quality"

The management and monitoring of clinical trials represents a constant challenge for nurses, who must have in-depth knowledge of the management and regulation of clinical studies. Among the main challenges are the correct planning and execution of trials, compliance with international regulations and the adoption of innovative technologies for data collection and analysis. Added to this is the need to guarantee patient safety and transparency in research processes, which are determining factors in the approval of new treatments and medical advances. In this context, having advanced skills in this area is essential to optimize the efficiency and quality of Clinical Trials.

For this reason, TECH presents an exclusive MBA in Clinical Trial Management and Monitoring for Nursing. Developed by experts in the field, this university program covers everything from the ethical and legal principles of research to the operational management of clinical trials. It also delves into the application of advanced methodologies for data collection and the use of artificial intelligence in the assessment of results. Thanks to this comprehensive approach, graduates will be qualified to lead research teams, supervise each phase of the trial and guarantee compliance with the quality standards demanded by the pharmaceutical industry and regulatory bodies.

In terms of methodology, this university degree is based on the innovative Relearning method, of which TECH is a pioneer. This system allows for the efficient and dynamic assimilation of the most complex concepts. Furthermore, access to this teaching methodology facilitates study from any device with an Internet connection, providing specialists with state-of-the-art multimedia material, real case studies and interactive analysis.

In addition, distinguished Guest Directors will deliver rigorous Masterclasses, providing key strategic knowledge for the development of advanced skills.

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

- The development of case studies presented by experts in Clinical Trials Management and Monitoring
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- Practical exercises where self-assessment can be used to improve learning
- Special emphasis on innovative methodologies in Clinical Trials Management and Monitoring
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- Content that is accessible from any fixed or portable device with an Internet connection

Renowned international Guests Directors will offer intensive Masterclasses on the latest trends in the Management of Clinical Trials for Nursing"

Thanks to TECH's innovative Relearning system, you will optimize your study time, focusing on the most key concepts of the syllabus"

You will master the most advanced methods for evaluating efficiency in clinical trials.

You will optimize Clinical Trial monitoring processes, guaranteeing quality, safety and efficacy in research.

Its teaching staff includes professionals from the field of Clinical Trials Management and Monitoring, who bring their work experience to the program, as well as renowned specialists from leading companies 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 an immersive learning experience designed to prepare for real-life situations.

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

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Why Study at TECH?

TECH is the world's largest online university. With an impressive catalog of more than 14,000 university programs available in 11 languages, it is positioned as a leader in employability, with a 99% job placement rate. In addition, it relies on an enormous faculty of more than 6,000 professors of the highest international renown.

Study at the world's largest online university and guarantee your professional success. The future starts at TECH"

The world's best online university, according to FORBES

The prestigious Forbes magazine, specialized in business and finance, has highlighted TECH as "the best online university in the world" This is what they have recently stated in an article in their digital edition in which they echo the success story of this institution, "thanks to the academic offer it provides, the selection of its teaching staff, and an innovative learning method oriented to form the professionals of the future".

The best top international faculty

TECH's faculty is made up of more than 6,000 professors of the highest international prestige. Professors, researchers and top executives of multinational companies, including Isaiah Covington, performance coach of the Boston Celtics; Magda Romanska, principal investigator at Harvard MetaLAB; Ignacio Wistumba, chairman of the department of translational molecular pathology at MD Anderson Cancer Center; and D.W. Pine, creative director of TIME magazine, among others.

The world's largest online university

TECH is the world's largest online university. We are the largest educational institution, with the best and widest digital educational catalog, one hundred percent online and covering most areas of knowledge. We offer the largest selection of our own degrees and accredited online undergraduate and postgraduate degrees. In total, more than 14,000 university programs, in ten different languages, making us the largest educational institution in the world.

The most complete syllabuses on the university scene

TECH offers the most complete syllabuses on the university scene, with programs that cover fundamental concepts and, at the same time, the main scientific advances in their specific scientific areas. In addition, these programs are continuously updated to guarantee students the academic vanguard and the most demanded professional skills. and the most in-demand professional competencies. In this way, the university's qualifications provide its graduates with a significant advantage to propel their careers to success.

A unique learning method

TECH is the first university to use Relearning in all its programs. This is the best online learning methodology, accredited with international teaching quality certifications, provided by prestigious educational agencies. In addition, this innovative academic model is complemented by the "Case Method", thereby configuring a unique online teaching strategy. Innovative teaching resources are also implemented, including detailed videos, infographics and interactive summaries.

The official online university of the NBA

TECH is the official online university of the NBA. Thanks to our agreement with the biggest league in basketball, we offer our students exclusive university programs, as well as a wide variety of educational resources focused on the business of the league and other areas of the sports industry. Each program is made up of a uniquely designed syllabus and features exceptional guest hosts: professionals with a distinguished sports background who will offer their expertise on the most relevant topics.

Leaders in employability

TECH has become the leading university in employability. Ninety-nine percent of its students obtain jobs in the academic field they have studied within one year of completing any of the university's programs. A similar number achieve immediate career enhancement. All this thanks to a study methodology that bases its effectiveness on the acquisition of practical skills, which are absolutely necessary for professional development.

Google Premier Partner

The American technology giant has awarded TECH the Google Premier Partner badge. This award, which is only available to 3% of the world's companies, highlights the efficient, flexible and tailored experience that this university provides to students. The recognition not only accredits the maximum rigor, performance and investment in TECH's digital infrastructures, but also places this university as one of the world's leading technology companies.

The top-rated university by its students

Students have positioned TECH as the world's top-rated university on the main review websites, with a highest rating of 4.9 out of 5, obtained from more than 1,000 reviews. These results consolidate TECH as the benchmark university institution at an international level, reflecting the excellence and positive impact of its educational model.

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Syllabus

The syllabus of this MBA has been developed by specialists in Management and Monitoring of Clinical Trials. As such, this university program will cover key subjects such as drug development, the management and supervision of clinical trials, ethical and legal regulations, and biostatistics applied to research. It will also delve into strategic leadership and talent management within the healthcare sector. Thanks to this approach, graduates will be prepared to lead research projects and guarantee excellence in clinical processes.

You will develop advanced skills in Applied Biostatistics, facilitating informed decision making"

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. Pre-clinical Phase
- 1.1.5. Clinical Phase
- 1.1.6. Approval and Registration

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

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

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

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

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

1.7. Uses in Special Situations
- 1.7.1. Introduction
- 1.7.2. 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 According to their 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 Cts (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 CTs (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. Notification of Adverse Events
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. Check Out
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. Pre-selection Visit
  - 3.3.1.2. Initiation Visit
  - 3.3.1.3. Monitoring Visit
  - 3.3.1.4. Audits and Inspections
  - 3.3.1.5. Close-Out 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 Hospital Urology Service (II)
- 3.5.1. Patient Retention
  - 3.5.1.1. Post-Treatment Monitoring Visits
  - 3.5.1.2. Longterm 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
- 3.5.4. Quality Control and Compliance
  - 3.5.4.1. Authorization of Subjects Protected Health Information
  - 3.5.4.2. Retention of Study Records and Files
  - 3.5.4.3. Data Collection Notebooks
  - 3.5.4.4. Protocol Amendments
- 3.5.6. Conclusions

3.6. Approval of a Clinical Trial to the Urology Service. Steps to Follow
- 3.6.1. Feasibility
- 3.6.2. Pre-selection 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. Education
- 3.6.8. Delegation of Functions
- 3.6.9. Visit to Other Services Involved
- 3.5.10. Closure of 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. Clinical 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. Startup 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. Controlling Temperature
- 4.10.4. General Deviation Procedure

Module 5. Monitoring of Clinical Trials (II)

5.1. Follow-Up Visit
- 5.1.1. Preparing for the Visit: Coordination and Review of Essential Documents prior to the Visit
- 5.1.2. Development for the Visit: Verification of Documentation, Medication Control and Analysis of Sample Storage
- 5.1.3. Report and Follow-up: Preparation of Monitoring and Follow-up Reports on Problems Detected During the Visit

5.2. Close-Out Visit
- 5.2.1. Definition and Reasons: Reasons for Conducting the Close-Out Visit, Such as Completion or Withdrawal from Recruitment
- 5.2.2. Procedures During the Visit: Verification of Final data, Documentation and Formal Closure of the Trial
- 5.2.3. Management of Deviations and Findings: Procedures for the Identification and Resolution of Problems During the Close-Out Visit

5.3. Management of Queries and Database Crashes
- 5.3.1. Generation of Queries: Types of Queries (Automatic, Monitor or External) and Their Resolution
- 5.3.2. Status of Queries: Different Query Statuses (Open, Pending and Closed) and Their Management
- 5.3.3. Database Crashes: Procedures for Database Crashes and Resolution of Common Errors

5.4. Management of Adverse Events and SAE
- 5.4.1. Definition of SAE: Adverse Event and Adverse Reaction, SAE and SUSAR
- 5.4.2. SAE Reporting: Reporting Procedure, Periodic Reports and Corrective Actions
- 5.4.3. Post-SAE Management: Impact Analysis and Correction of SAEs within the Trial

5.5. Standard Operating Procedures (SOPs)
- 5.5.1. Drafting of SOPs: Structure of Standard Operating Procedures (SOPs) for Clinical Trials
- 5.5.2. Implementation of SOPs: Application of SOPs During Start-up, Monitoring and Close-Out Visits
- 5.5.3. Post-visit Follow-up: Procedures for Follow-up After Monitoring and Close-Out Visits

5.6. Quality Guarantee: Audits and Inspections
- 5.6.1. Types of Audits: Internal and External Audits and their Relevance in Compliance with Standards
- 5.6.2. Preparing for Audits: Methods to Ensure a Successful Audit and the Management of Findings
- 5.6.3. Management of Findings: Corrective Actions Following an Audit or Inspection

5.7. Protocol Deviations
- 5.7.1. Identification of Deviations: Types of Deviations and Their Impact on Trials
- 5.7.2. Management of Deviations: Procedures for Resolving and Documenting Protocol Deviations

5.8. Source and Essential Documents
- 5.8.1. Source Document Types: Essential Documents such as Case Reports and Researcher's Reports
- 5.8.2. Source Document Management: Procedures for Storing and Maintaining Essential Documents
- 5.8.3. Handling Documentation Errors: Methods for Correcting and Validating Source Documentation

Module 6. Coordination of Clinical Trials (I)

6.1. The Researcher's File - General Aspects
- 6.1.1. What is the Researcher's File?: Definition and Purpose
- 6.1.2. Type of Documentation: Types of Documents that the File Should Contain and Their Justification
- 6.1.3. Storage Time: Recommended Duration for the Storage of Information in the File

6.2. Contract
- 6.2.1. Original Copies: Requirements for Contracts and Their Retention
- 6.2.2. Amendments: Procedure for the Modification of Contracts during the Trial

6.3. Ethics Committees
- 6.3.1. Approvals: Documentation Required for Approval by Ethics Committees
- 6.3.2. Amendments: Procedure for Approval of Amendments by Ethics Committees

6.4. Regulatory Authorities
- 6.4.1. Approvals: Requirements for Approvals from Regulatory Authorities
- 6.4.2. Modifications: Procedures for Modification of Approved Documents
- 6.4.3. Monitoring and Final Reports: Documentation of Reports and their Management

6.5. Civil Liability Insurance
- 6.5.1. Insurance Coverage: Documentation Related to Civil Liability Insurance

6.6. Documentation Associated with the Research Team
- 6.6.1. Researcher's CV: Requirements and Format for the Research Team's Curricula Vitae
- 6.6.2. Certificate of Good Clinical Practice (GCP): Documentation on the Required Certifications
- 6.6.3. Specific Training Certificates: Documents Required to Validate the Research Team's Training
- 6.6.4. Signed Declaration of the Researcher - "Financial Disclosure": Importance of the Declaration of Financial Interests
- 6.6.5. Delegation of Tasks: Documentation and Procedures for the Delegation of Tasks within the Research Team

6.7. Study Protocol and Monitoring
- 6.7.1. Protocol Versions, Summary and Pocket Guides: Documentation and Changes to the Protocol, as well as Guidelines for the Team
- 6.7.2. Protocol: Structure and Details of the Study Protocol
- 6.7.3. Protocol Amendments: Procedures and Management of Protocol Modifications
- 6.7.4. Protocol Signature Sheet: Documentation to be Signed by All Those Involved in the Protocol

6.8. Patient-Related Material
- 6.8.1. Patient Information Sheet and Informed Consent: Duplicates and Copies for Signature
- 6.8.2. Modifications to Consent: Documentation of Changes and Required Signatures
- 6.8.3. Study Participation Cards: Information for Participating Patients
- 6.8.4. Information for Primary Care Physicians: Informative Documents to Be Given to Doctors
- 6.8.5. Questionnaires: Tools for Collecting Patient Data

6.9. Patient Forms, Monitoring Visits
- 6.9.1. Patient Screening Form: Patient Pre-selection Documentation
- 6.9.2. Patient Recruitment and Identification Form: Procedures for Patient Recruitment and Identification
- 6.9.3. Visit Logs and Reports Form: Documents Needed to Record Visits and Data Obtained

6.10. Data Collection Notebooks (DCNs)
- 6.10.1. Types of DCNs: Different Types of Notebooks and Their Usefulness
- 6.10.2. Guide or Manual for Data Entry in the DCN: Instructions for the Proper Use of the DCN
- 6.10.3. Copy of DCN: Procedures for Copying and Storing the DCN

6.11. Investigator's Brochure (Studies with Medical Devices) or Fact Sheet (Clinical Trials with Medication)
- 6.11.1. Investigator's Manual: Guide for the Investigator on the Management and Monitoring of the Study
- 6.11.2. Technical Data Sheet for Trial Drugs: Documentation on the Drugs used in the Trial (If they are Already on the Market)
- 6.11.3. Instructions for the Control of Specific Parameters (e.g. Temperature): Procedures for the Control of Critical Variables
- 6.11.4. Instructions for the Return of Medication or Medical Devices: Procedure for the Handling of Unused Products

6.12. Material Related to Laboratory and Specific Procedures
- 6.12.1. Central Laboratories and Sample Shipping Documents: Documentation for the Management of Samples in Central Laboratories
- 6.12.2. Local Laboratory: Qualification Certificates and Ranks
- 6.12.3. Instructions for Acquiring and/or Processing Medical Images: Procedures for the Handling of Medical Images
- 6.12.4. Sample and Material Shipment: Procedures and Documents Required for the Shipment of Samples

6.13. Security
- 6.13.1. Adverse Events and Serious Adverse Events: Documentation and Procedures for Notification and Monitoring
- 6.13.2. Notification Instructions: Procedures for the Notification of Adverse Events
- 6.13.3. Relevant Safety Correspondence: Management of Safety-Related Communication in the Trial

6.14. Others
- 6.14.1. Contact Details: Information on Key Contact Persons in the Trial
- 6.14.2. "Note to File": Internal Documentation and Notes Relevant to the File
- 6.14.3. Correspondence with the Promoter: Documentation Exchanged with the Study Sponsor
- 6.14.4. Acknowledgements of Receipt: Procedure for Managing Acknowledgements of Receipt
- 6.14.5. Newsletter: Newsletters on the Study's Progress

Module 8. 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. Delegation of Tasks
  - 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. Competencies
- 7.2.3. Clinical Trial 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

7.5. Good Clinical Practice:
- 7.5.1. Origin of Good Clinical Practices
- 7.5.2. How to Get Certified?
- 7.5.3. Expiration

7.6. Suitability of the Research Team:
- 7.6.1. Who Signs the Document?
- 7.6.2. Presentation to Ethics Committee

7.7. Suitability of Facilities:
- 7.7.1. Who Signs the Document?
- 7.7.2. Presentation to Ethics Committee

7.8. Calibration Certificates:
- 7.8.1. Calibration
- 7.8.2. Calibration Equipment
- 7.8.3. Valid Certifications
- 7.8.4. Expiration

7.9. Other Training
- 7.9.1. Necessary Certifications According Protocol

7.10. Main Functions Trial Coordinator:
- 7.10.1. Documentation Preparation
  - 7.10.1.1. Documentation Requested for Approval of the Study at the Center
- 7.10.2. Investigator Meeting
  - 7.10.2.1. Importance
  - 7.10.2.2. Attendees
- 7.10.3. Initiation Visit:
  - 7.10.3.1. Duties of the Coordinator
  - 7.10.3.2. Functions of the Principal Investigator and Subinvestigators
  - 7.10.3.3. Promoter
  - 7.10.3.4. Monitor
- 7.10.4. Monitoring Visit:
  - 7.10.4.1. Preparation After a Monitoring Visit
  - 7.10.4.2. Functions During the Monitoring Visit
- 7.10.5. End-Of-Study Visit:
  - 7.10.5.1. Storage of the Researchers File

7.11. Relationship with the Patient:
- 7.11.1. Preparation of Visits
  - 7.11.1.1. Consents and Amendments
  - 7.11.1.2. Visit Window
  - 7.11.1.3. Identify the Responsibilities of the Investigation Team during the Visit
  - 7.11.1.4. Visit Calculator
  - 7.11.1.5. Preparation of Documentation to be Used During the Visit
- 7.11.2. Complementary Tests:
  - 7.11.2.1. Analysis
  - 7.11.2.2. Chest X-Ray
  - 7.11.2.3. Electrocardiogram
- 7.11.3. Calendar of Visits
  - 7.11.3.1. Example

7.12. Samples
- 7.12.1. Equipment and Materials Necessary
  - 7.12.1.1. Centrifuge
  - 7.12.1.2. Incubator
  - 7.12.1.3. Refrigerators
- 7.12.2. Processing of Samples
  - 7.12.2.1. General Procedure
  - 7.12.2.2. Example
- 7.12.3. Laboratory Kits
  - 7.12.3.1. What Are They?
  - 7.12.3.2. Expiration
- 7.12.4. Shipment of Samples:
  - 7.12.4.1. Sample Storage
  - 7.12.4.2. Ambient Temperature Shipment
  - 7.12.4.3. Shipping Frozen Samples

7.13. Data Collection Notebooks:
- 7.13.1. What Is It?
- 7.13.2. Types of Notebooks:
  - 7.13.2.1. Paper Notebook
  - 7.13.2.2. Electronic Notebook
  - 7.13.2.3. Specific Notebooks According to Protocol
- 7.13.3. How To Complete It?
  - 7.13.3.1. Example
- 7.13.4. Query
  - 7.13.4.1. What Is a Query?
  - 7.13.4.2. Resolution Time
  - 7.13.4.3. Who Can Open a Query?

7.14. Randomization Systems
- 7.14.1. What Is It?
- 7.14.2. Types of IWRS:
  - 7.14.2.1. Telephonics
  - 7.14.2.2. Electronics
- 7.14.3. Researcher Responsibilities vs. Research Team Responsibilities:
  - 7.14.3.1. Screening
  - 7.14.3.2. Randomization
  - 7.14.3.3. Scheduled Visits
  - 7.14.3.4. Unscheduled Visits
  - 7.14.3.5. Blinding Opening
- 7.14.4. Medication
  - 7.14.4.1. Who Receives the Medication?
  - 7.14.4.2. Drug Traceability
- 7.14.5. Return of Medication:
  - 7.14.5.1. Functions of the Research Team in the Return of Medication

7.15. Biological Treatments:
- 7.15.1. Coordination of Clinical Trials with Biologicals
  - 7.15.1.1. Biological Treatments
  - 7.15.1.2. Types of Treatment
- 7.15.2. Types of Studies:
  - 7.15.2.1. Biological vs. Placebo
  - 7.15.2.2. Biological vs. Biological
- 7.15.3. Biological Management
  - 7.15.3.1. Administration
  - 7.15.3.2. Traceability
- 7.15.4. Rheumatic Diseases
  - 7.15.4.1. Rheumatoid Arthritis
  - 7.15.4.2. Psoriatic Arthritis
  - 7.15.4.3. Lupus
  - 7.15.4.4. Scleroderma

Module 8. Monitoring 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. Monitoring of Adverse Reactions and Symptom Management in the Study Medication
- 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 a Statistical Analysis Plan?
- 9.7.3. Statistical Analysis Plan Parts

9.8. Intermediate Analysis
- 9.8.1. Reasons for an Early Termination 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

10.1. Statistical Review of a Protocol
- 10.10.1. Checklist
- 10.10.2. Frequent Errors in the Review of a Protocol

Module 10. Leadership, Ethics and Social Responsibility in Companies

10.1. Globalization and Governance
- 10.1.1. Governance and Corporate Governance
- 10.1.2. The Fundamentals of Corporate Governance in Companies
- 10.1.3. The Role of the Board of Directors in the Corporate Governance Framework

10.2. Leadership
- 10.2.1. Leadership. A Conceptual Approach
- 10.2.2. Leadership in Companies
- 10.2.3. The Importance of Leaders in Business Management

10.3. Cross-Cultural Management
- 10.3.1. Cross Cultural Management Concept
- 10.3.2. Contributions to Knowledge of National Cultures
- 10.3.3. Diversity Management

10.4. Management and Leadership Development
- 10.4.1. Concept of Management Development
- 10.4.2. Concept of Leadership
- 10.4.3. Leadership Theories
- 10.4.4. Leadership Styles
- 10.4.5. Intelligence in Leadership
- 10.4.6. The Challenges of Today's Leader

10.5. Business Ethics
- 10.5.1. Ethics and Morality
- 10.5.2. Business Ethics
- 10.5.3. Leadership and Ethics in Companies

10.6. Sustainability
- 10.6.1. Sustainability and Sustainable Development
- 10.6.2. The 2030 Agenda
- 10.6.3. Sustainable Companies

10.7. Corporate Social Responsibility
- 10.7.1. International Dimensions of Corporate Social Responsibility
- 10.7.2. Implementing Corporate Social Responsibility
- 10.7.3. The Impact and Measurement of Corporate Social Responsibility

10.8. Responsible Management Systems and Tools
- 10.8.1. CSR: The Corporate Social Responsibility
- 10.8.2. Essential Aspects for Implementing a Responsible Management Strategy
- 10.8.3. Steps for the Implementation of a Corporate Social Responsibility Management System
- 10.8.4. CSR Tools and Standards

10.9. Multinationals and Human Rights
- 10.9.1. Globalization, Multinational Companies and Human Rights
- 10.9.2. Multinational Corporations and International Law
- 10.9.3. Legal Instruments for Multinationals in the Area of Human Rights

10.10. Legal Environment and Corporate Governance
- 10.10.1. International Rules on Importation and Exportation
- 10.10.2. Intellectual and Industrial Property
- 10.10.3. International Labor Law

Module 11. People and Talent Management

11.1. Strategic People Management
- 11.1.1. Strategic Human Resources Management
- 11.1.2. Strategic People Management

11.2. Human Resources Management by Competencies
- 11.2.1. Analysis of the Potential
- 11.2.2. Remuneration Policy
- 11.2.3. Career/Succession Planning

11.3. Performance Evaluation and Performance Management
- 11.3.1. Performance Management
- 11.3.2. Performance Management: Objectives and Process

11.4. Innovation in Talent and People Management
- 11.4.1. Strategic Talent Management Models
- 11.4.2. Talent Identification, Training and Development
- 11.4.3. Loyalty and Retention
- 11.4.4. Proactivity and Innovation

11.5. Motivation
- 11.5.1. The Nature of Motivation
- 11.5.2. Expectations Theory
- 11.5.3. Needs Theory
- 11.5.4. Motivation and Financial Compensation

11.6. High-Performance Teams Development
- 11.6.1. High-Performance Teams: Self-Managed Teams
- 11.6.2. Methodologies for the Management of High-Performance Self-Managed Teams

11.7. Change Management
- 11.7.1. Change Management
- 11.7.2. Type of Change Management Processes
- 11.7.3. Stages or Phases in the Change Management Process

11.8. Negotiation and Conflict Management
- 11.8.1. Negotiation
- 11.8.2. Conflict Management
- 11.8.3. Crisis Management

11.9. Executive Communication
- 11.9.1. Internal and External Communication in the Corporate Environment
- 11.9.2. Communication Departments
- 11.9.3. The Person in Charge of Communication of the Company. The Profile of the Dircom

11.10. Productivity, Attraction, Retention and Activation of Talent
- 11.10.1. Productivity
- 11.10.2. Talent Attraction and Retention Levers

Module 12. Economic and Financial Management

12.1. Economic Environment
- 12.1.1. Macroeconomic Environment and the National Financial System
- 12.1.2. Financial Institutions
- 12.1.3. Financial Markets
- 12.1.4. Financial Assets
- 12.1.5. Other Financial Sector Entities

12.2. Executive Accounting
- 12.2.1. Basic Concepts
- 12.2.2. The Company's Assets
- 12.2.3. The Company's Liabilities
- 12.2.4. The Company's Net Worth
- 12.2.5. The Income Statement

12.3. Information Systems and Business Intelligence
- 12.3.1. Fundamentals and Classification
- 12.3.2. Cost Allocation Phases and Methods
- 12.3.3. Choice of Cost Center and Impact

12.4. Budget and Management Control
- 12.4.1. The Budget Model
- 12.4.2. The Capital Budget
- 12.4.3. The Operating Budget
- 12.4.5. Treasury Budget
- 12.4.6. Budget Monitoring

12.5. Financial Management
- 12.5.1. The Company's Financial Decisions
- 12.5.2. Financial Department
- 12.5.3. Cash Surpluses
- 12.5.4. Risks Associated with Financial Management
- 12.5.5. Financial Administration Risk Management

12.6. Financial Planning
- 12.6.1. Definition of Financial Planning
- 12.6.2. Actions to be Taken in Financial Planning
- 12.6.3. Creation and Establishment of the Business Strategy
- 12.6.4. The Cash Flow Table
- 12.6.5. The Working Capital Table

12.7. Corporate Financial Strategy
- 12.7.1. Corporate Strategy and Sources of Financing
- 12.7.2. Financial Products for Corporate Financing

12.8. Strategic Financing
- 12.8.1. Self-Financing
- 12.8.2. Increase in Equity
- 12.8.3. Hybrid Resources
- 12.8.4. Financing Through Intermediaries

12.9. Financial Analysis and Planning
- 12.9.1. Analysis of the Balance Sheet
- 12.9.2. Analysis of the Income Statement
- 12.9.3. Profitability Analysis

12.10. Analyzing and Solving Cases/Problems
- 12.10.1. Financial Information on Industria de Diseño y Textil, S.A. (INDITEX)

Module 13. Commercial and Strategic Marketing Management

13.1. Commercial Management
- 13.1.1. Conceptual Framework of Commercial Management
- 13.1.2. Business Strategy and Planning
- 13.1.3. The Role of Sales Managers

13.2. Marketing
- 13.2.1. The Concept of Marketing
- 13.2.2. Basic Elements of Marketing
- 13.2.3. Marketing Activities of the Company

13.3. Strategic Marketing Management
- 13.3.1. The Concept of Marketing Strategic
- 13.3.2. Concept of Strategic Marketing Planning
- 13.3.3. Stages in the Process of Strategic Marketing Planning

13.4. Digital Marketing and E-commerce
- 13.4.1. Digital Marketing and E-commerce Objectives
- 13.4.2. Digital Marketing and Media Used
- 13.4.3. E-Commerce. General Context
- 13.4.4. Categories of E-Commerce
- 13.4.5. Advantages and Disadvantages of E-Commerce Vs. Traditional Commerce

13.5. Digital Marketing to Reinforce a Brand
- 13.5.1. Online Strategies to Improve Your Brand's Reputation
- 13.5.2. Branded Content and Storytelling

13.6. Digital Marketing to Attract and Retain Customers
- 13.6.1. Loyalty and Engagement Strategies through the Internet
- 13.6.2. Visitor Relationship Management
- 13.6.3. Hypersegmentation

13.7. Managing Digital Campaigns
- 13.7.1. What is a Digital Advertising Campaign?
- 13.7.2. Steps to Launch an Online Marketing Campaign
- 13.7.3. Mistakes in Digital Advertising Campaigns

13.8. Sales Strategy
- 13.8.1. Sales Strategy
- 13.8.2. Sales Methods

13.9. Corporate Communication
- 13.9.1. Concept
- 13.9.2. The Importance of Communication in the Organization

13.9.3. Type of Communication in the Organization
13.9.4. Functions of Communication in the Organization
13.9.5. Elements of Communication
13.9.6. Communication Problems
13.9.7. Communication Scenarios
13.10. Digital Communication and Reputation
13.10.1. Online Reputation
13.10.2. How to Measure Digital Reputation?
13.10.3. Online Reputation Tools
13.10.4. Online Reputation Report
13.10.5. Online Branding

Module 14. Executive Management

14.1. General Management
14.1.1. The Concept of General Management
14.1.2. The Role of the General Manager
14.1.3. The General Director and its Responsibilities
14.1.4. Transforming the Work of Management
14.2. Manager Functions. Organizational Culture and Approaches
14.2.1. Manager Functions. Organizational Culture and Approaches
14.3. Operations Management
14.3.1. The Importance of Management
14.3.2. Value Chain
14.3.3. Quality Management
14.4. Public Speaking and Spokesperson Training
14.4.1. Interpersonal Communication
14.4.2. Communication Skills and Influence
14.4.3. Communication Barriers
14.5. Personal and Organizational Communications Tools
14.5.1. Interpersonal Communication
14.5.2. Interpersonal Communication Tools
14.5.3. Communication in the Organization
14.5.4. Tools in the Organization
14.6. Communication in Crisis Situations
14.6.1. Crisis
14.6.2. Phases of the Crisis
14.6.3. Messages: Contents and Moments
14.7. Preparation of a Crisis Plan
14.7.1. Analysis of Possible Problems
14.7.2. Planning
14.7.3. Adequacy of Personnel
14.8. Emotional Intelligence
14.8.1. Emotional Intelligence and Communication
14.8.2. Assertiveness, Empathy and Active Listening
14.8.3. Self-Esteem and Emotional Communication
14.9. Personal Branding
14.9.1. Strategies for Personal Brand Development
14.9.2. Personal Branding Laws
14.9.3. Tools for Creating Personal Brands
14.10. Leadership and Team Management
14.10.1. Leadership and Leadership Styles
14.10.2. Leader Capabilities and Challenges
14.10.3. Managing Change Processes
14.10.4. Managing Multicultural Teams

You will specialize in the Financial Management of Clinical Trial projects, guaranteeing their profitability and viability"

04

Teaching Objectives

This degree has been developed to prepare nursing professionals to manage and monitor clinical trials with a comprehensive approach. The teaching objectives include the development of advanced skills in trial management, an understanding of ethical and legal regulations, and the application of biostatistical techniques for the evaluation of results. In turn, graduates will be prepared to lead multidisciplinary teams, manage resources efficiently and guarantee the safety and well-being of patients during clinical trials.

You will implement cutting-edge clinical data analysis strategies, using innovative tools for the evaluation of results"

General Objectives

- Develop advanced skills in the comprehensive management of clinical trials, from planning to execution and supervision.
- Apply advanced technological tools, such as biostatistics and clinical data analysis, to optimize decision making in research
- Promote innovation in the development of drugs and treatments, integrating advanced methodologies and cutting-edge strategies in clinical research
- Foster efficient resource management in clinical trials to maximize productivity and reduce costs without compromising quality
- Develop skills in leadership and talent management, applying them in clinical research environments to strengthen work teams and improve results
- Promote ethics and social responsibility in the management of Clinical Trials, guaranteeing transparency and integrity in all phases of research

Specific Objectives

Module 1. Drug Research and Development

- Understand the process of research and development of medicines, from the conception of the idea to commercialization
- Identify the main scientific and technological advances applied to the development of new drugs

Module 2. Clinical Trials (I)

- Understand the fundamentals and phases of clinical trials, as well as the most commonly used methodologies
- Apply the knowledge acquired in the design and planning of initial Clinical Trials

Module 3. Clinical Trials (II)

- Analyze the challenges and advanced methodologies in the execution of intermediate and final phase clinical trials
- Evaluate the effectiveness of treatments in various phases of the trial and manage data collection

Module 4. Monitoring of Clinical Trials (I)

- Develop skills to monitor the execution of Clinical Trials, identifying possible deviations and risks
- Ensure the correct implementation of standard operating procedures (SOP) in the monitoring of clinical trials

Module 5. Monitoring of Clinical Trials (II)

- Apply advanced techniques in the monitoring of clinical data and the use of technology to ensure quality
- Identify and solve complex problems in the monitoring phase of clinical trials

Module 6. Coordination of Clinical Trials (I)

- Manage the logistical coordination of clinical trials, from preparation to execution
- Develop a strategic approach for the efficient organization of Clinical Trials in their initial phase

Module 7. Coordination of Clinical Trials (II)

- Manage and coordinate multidisciplinary teams in the advanced phase of clinical trials
- Implement action plans to resolve conflicts or unforeseen events during the execution of the Clinical Trial

Module 8. Monitoring of Patients in Clinical Trials

- Develop strategies for the adequate monitoring of patients during clinical trials, ensuring their well-being
- Analyze monitoring data to evaluate the efficacy and safety of the treatment administered

Module 9. Biostatistics

- Apply biostatistical techniques to interpret clinical data and analyze results
- Use advanced statistical tools to evaluate the significance of results obtained in clinical trials

Module 10. Leadership, Ethics and Social Responsibility in Companies

- Develop ethical leadership skills in the management of research teams and clinical trials
- Promote social responsibility and sustainability in the management of clinical trials

Module 11. People and Talent Management

- Manage multidisciplinary teams efficiently, promoting motivation and performance
- Apply talent development strategies to optimize the performance of professionals in clinical trials

Module 12. Economic and Financial Management

- Develop skills in the economic and financial management of clinical trial projects
- Evaluate and manage budgets, cost control and profitability in clinical research

Module 13. Commercial and Strategic Marketing Management

- Develop effective commercial strategies for the promotion and dissemination of clinical trial results
- Apply strategic marketing techniques to position new drugs on the market

Module 14. Executive Management

- Develop executive skills for managing teams and projects in the field of clinical trials
- Implement strategic management plans to optimize the effectiveness and results of clinical trials

You will acquire skills in biostatistics, which will enable you to accurately evaluate results"

05

Career Opportunities

Upon completion of this MBA in Clinical Trials Management and Monitoring for Nursing, professionals will have the opportunity to acquire advanced skills to take on leadership roles in clinical research. Upon completion of the university program, graduates will be qualified to manage Clinical Trials in pharmaceutical companies, hospitals, research centers and universities, occupying positions such as Clinical Trial Coordinators, Research Project Managers or Monitoring Managers.

In this way, they will be able to work as Specialized Consultants, optimizing the planning and execution of research, ensuring regulatory compliance and maximizing resources throughout the research process.

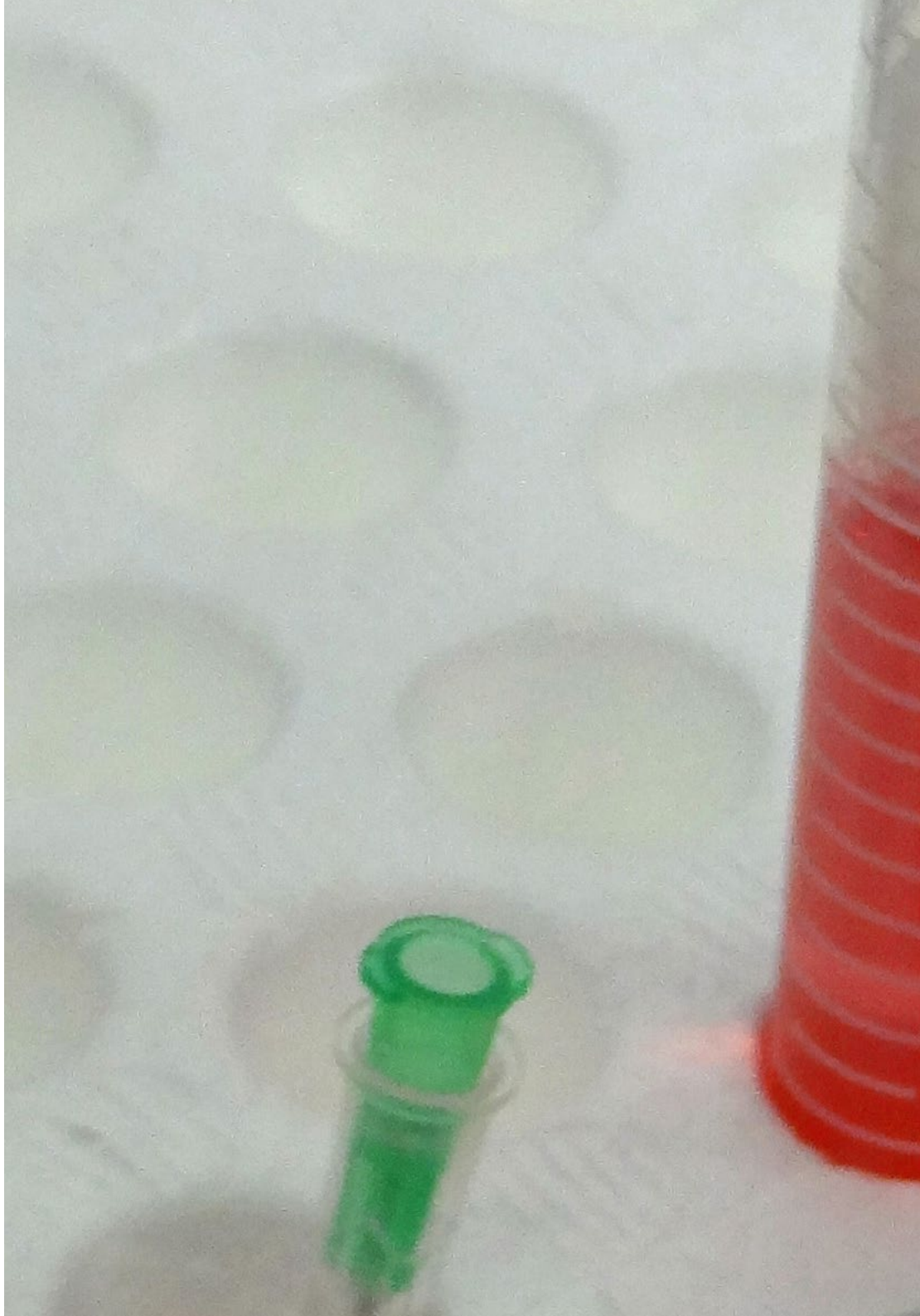
You will manage clinical trials with a comprehensive approach, optimizing resources and guaranteeing patient safety during the research process.

Graduate Profile

Graduates will be highly skilled professionals capable of leading and coordinating clinical trials, with a focus on efficiency, ethics and quality of care. They will also have specialized knowledge of the main areas of drug research and development, from biostatistics to the monitoring of clinical trials, enabling them to manage multidisciplinary teams and optimize resources in research projects. On the other hand, they will be experts in the implementation of international regulations and standards, capable of guaranteeing the safety and well-being of patients in all the studies in which they participate.

You will implement international regulations and standards, successfully leading initiatives that promote efficiency in Clinical Research.

- **Efficient Management of Clinical Trials:** Ability to coordinate and monitor clinical trials, guaranteeing compliance with deadlines, budgets and international regulations
- **Research Decision Making:** Ability to make strategic decisions based on scientific and clinical data, optimizing resources and improving the quality of trials
- **Application of Regulations and Bioethics:** Mastery of ethical and legal regulations in clinical research, guaranteeing patient safety and compliance with international standards
- **Leadership in Research Projects:** Ability to lead multidisciplinary teams, promoting collaboration and achieving common objectives in the development of clinical trials



After completing the program, you will be able to use your knowledge and skills in the following positions:

1. **Clinical Trial Director:** Responsible for the planning, execution and supervision of clinical trials, ensuring compliance with international regulations and the quality of the studies.
2. **Clinical Research Coordinator:** Responsible for the operational management of clinical trials, facilitating communication between research teams, sponsors and regulatory bodies.
3. **Clinical Trial Monitor:** Professional specialized in supervising the development of clinical trials, verifying the correct application of protocols and guaranteeing the integrity of the data.
4. **Clinical Trial Management Consultant:** Advisor to institutions and pharmaceutical companies in the optimization of clinical research processes, ensuring efficiency and regulatory compliance.
5. **Specialist in Bioethics and Clinical Regulation:** Responsible for guaranteeing compliance with ethical principles and regulations in clinical research, protecting the safety and rights of patients.
6. **Quality Manager in Clinical Research:** Professional dedicated to the implementation and supervision of quality control systems in clinical trials, ensuring the validity of the results obtained.
7. **Clinical Trial Project Manager:** Responsible for the strategic planning and resource management of clinical trial projects, optimizing time and costs.
8. **Biostaticians for Clinical Trials:** Specialist in the analysis of clinical data, contributing to the interpretation of results and decision making based on scientific evidence.

06

Study Methodology

TECH is the world's first university to combine the **case study** methodology with **Relearning**, a 100% online learning system based on guided repetition.

This disruptive pedagogical strategy has been conceived to offer professionals the opportunity to update their knowledge and develop their skills in an intensive and rigorous way. A learning model that places students at the center of the educational process giving them the leading role, adapting to their needs and leaving aside more conventional methodologies.

TECH will prepare you to face new challenges in uncertain environments and achieve success in your career"

The student: the priority of all TECH programs

In TECH's study methodology, the student is the main protagonist.
The teaching tools of each program have been selected taking into account the demands of time, availability and academic rigor that, today, not only students demand but also the most competitive positions in the market.

With TECH's asynchronous educational model, it is students who choose the time they dedicate to study, how they decide to establish their routines, and all this from the comfort of the electronic device of their choice. The student will not have to participate in live classes, which in many cases they will not be able to attend. The learning activities will be done when it is convenient for them. They can always decide when and from where they want to study.

"At TECH you will NOT have live classes (which you might not be able to attend)"

The most comprehensive study plans at the international level

TECH is distinguished by offering the most complete academic itineraries on the university scene. This comprehensiveness is achieved through the creation of syllabi that not only cover the essential knowledge, but also the most recent innovations in each area.

By being constantly up to date, these programs allow students to keep up with market changes and acquire the skills most valued by employers. In this way, those who complete their studies at TECH receive a comprehensive education that provides them with a notable competitive advantage to further their careers.

And what's more, they will be able to do so from any device, pc, tablet or smartphone.

> *TECH's model is asynchronous, so it allows you to study with your pc, tablet or your smartphone wherever you want, whenever you want and for as long as you want"*

Case Studies and Case Method

The case method has been the learning system most used by the world's best business schools. Developed in 1912 so that law students would not only learn the law based on theoretical content, its function was also to present them with real complex situations. In this way, they could make informed decisions and value judgments about how to resolve them. In 1924, Harvard adopted it as a standard teaching method.

With this teaching model, it is students themselves who build their professional competence through strategies such as Learning by Doing or Design Thinking, used by other renowned institutions such as Yale or Stanford.

This action-oriented method will be applied throughout the entire academic itinerary that the student undertakes with TECH. Students will be confronted with multiple real-life situations and will have to integrate knowledge, research, discuss and defend their ideas and decisions. All this with the premise of answering the question of how they would act when facing specific events of complexity in their daily work.

Relearning Methodology

At TECH, case studies are enhanced with the best 100% online teaching method: Relearning.

This method breaks with traditional teaching techniques to put the student at the center of the equation, providing the best content in different formats. In this way, it manages to review and reiterate the key concepts of each subject and learn to apply them in a real context.

In the same line, and according to multiple scientific researches, reiteration is the best way to learn. For this reason, TECH offers between 8 and 16 repetitions of each key concept within the same lesson, presented in a different way, with the objective of ensuring that the knowledge is completely consolidated during the study process.

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.

A 100% online Virtual Campus with the best teaching resources

In order to apply its methodology effectively, TECH focuses on providing graduates with teaching materials in different formats: texts, interactive videos, illustrations and knowledge maps, among others. All of them are designed by qualified teachers who focus their work on combining real cases with the resolution of complex situations through simulation, the study of contexts applied to each professional career and learning based on repetition, through audios, presentations, animations, images, etc.

The latest scientific evidence in the field of Neuroscience points to the importance of taking into account the place and context where the content is accessed before starting a new learning process. Being able to adjust these variables in a personalized way helps people to remember and store knowledge in the hippocampus to retain it in the long term. This is a model called Neurocognitive context-dependent e-learning that is consciously applied in this university qualification.

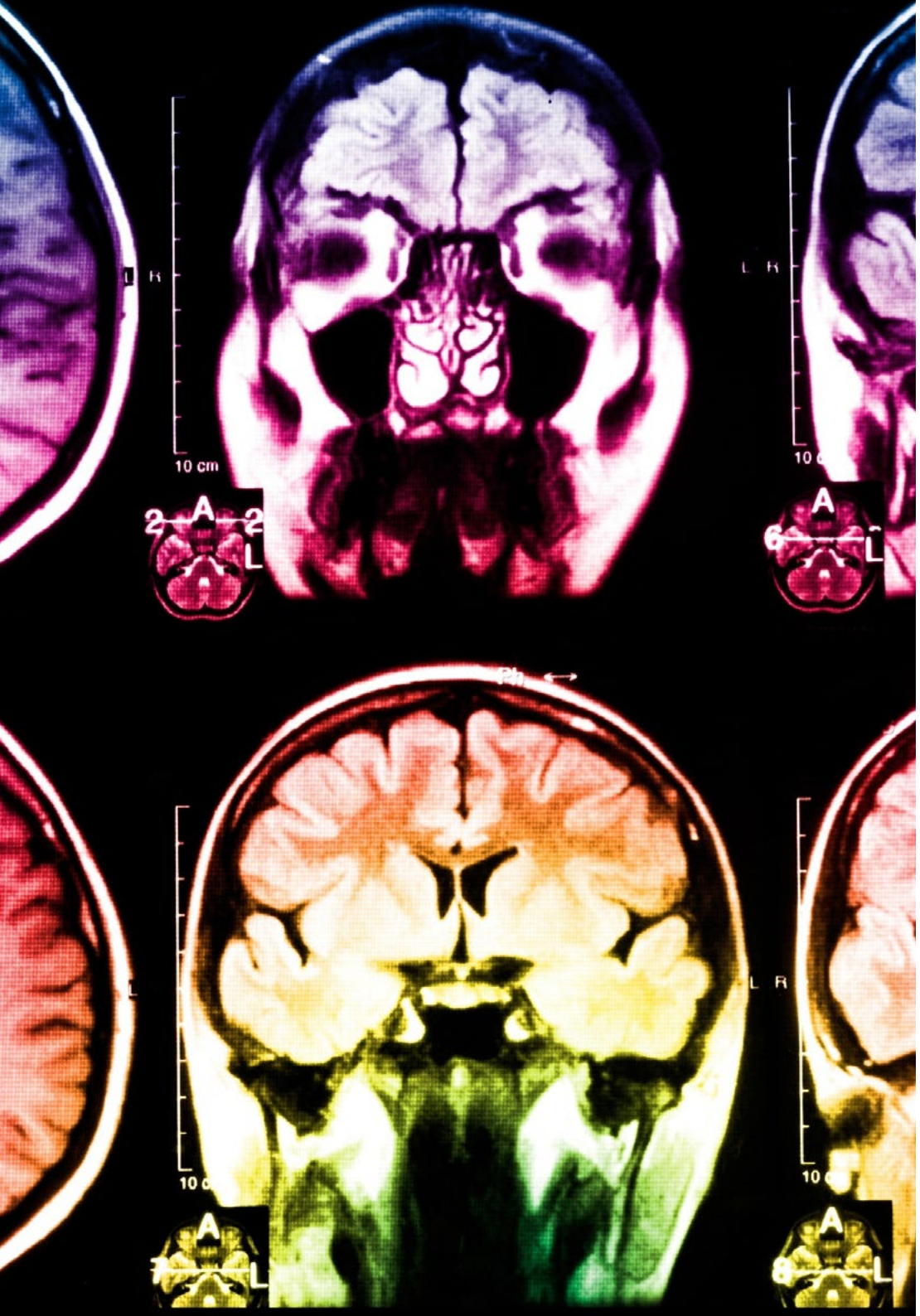
In order to facilitate tutor-student contact as much as possible, you will have a wide range of communication possibilities, both in real time and delayed (internal messaging, telephone answering service, email contact with the technical secretary, chat and videoconferences).

Likewise, this very complete Virtual Campus will allow TECH students to organize their study schedules according to their personal availability or work obligations. In this way, they will have global control of the academic content and teaching tools, based on their fast-paced professional update.

The online study mode of this program will allow you to organize your time and learning pace, adapting it to your schedule"

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

1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that assess real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts are understood more efficiently, given that the example situations are based on real-life.
4. Students like to feel that the effort they put into their studies is worthwhile. This then translates into a greater interest in learning and more time dedicated to working on the course.



The university methodology top-rated by its students

The results of this innovative teaching model can be seen in the overall satisfaction levels of TECH graduates.

The students' assessment of the teaching quality, the quality of the materials, the structure of the program and its objectives is excellent. Not surprisingly, the institution became the top-rated university by its students according to the global score index, obtaining a 4.9 out of 5.

Access the study contents from any device with an Internet connection (computer, tablet, smartphone) thanks to the fact that TECH is at the forefront of technology and teaching.

You will be able to learn with the advantages that come with having access to simulated learning environments and the learning by observation approach, that is, Learning from an expert.

As such, the best educational materials, thoroughly prepared, will be available in this program:

Study Material

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

This content is then adapted in an audiovisual format that will create our way of working online, with the latest techniques that allow us to offer you high quality in all of the material that we provide you with.

Practicing Skills and Abilities

You will carry out activities to develop specific competencies and skills in each thematic field. Exercises and activities to acquire and develop the skills and abilities that a specialist needs to develop within the framework of the globalization we live in.

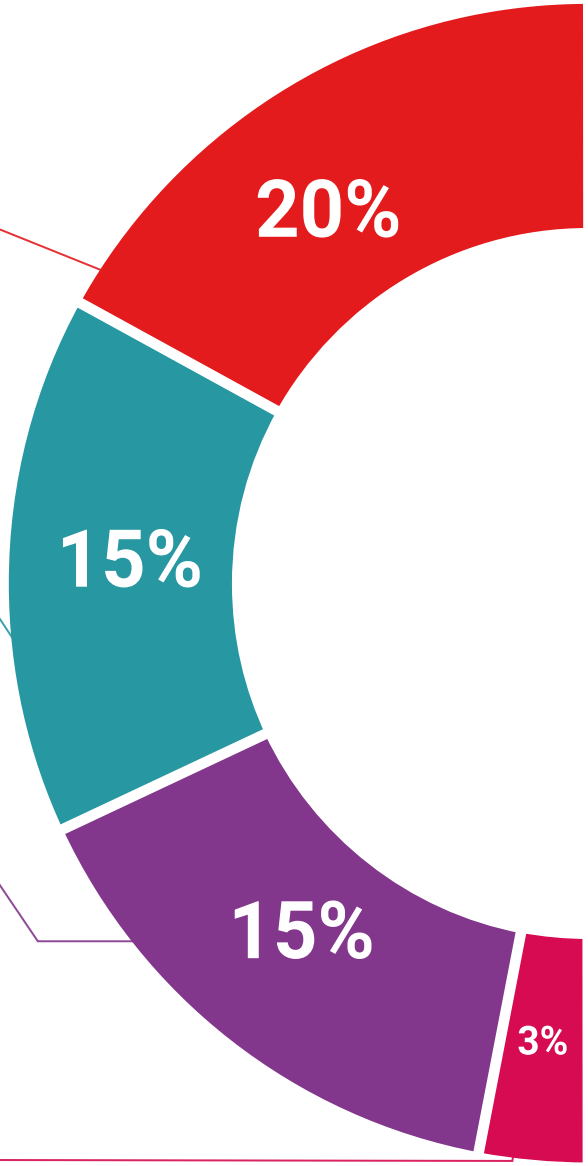
Interactive Summaries

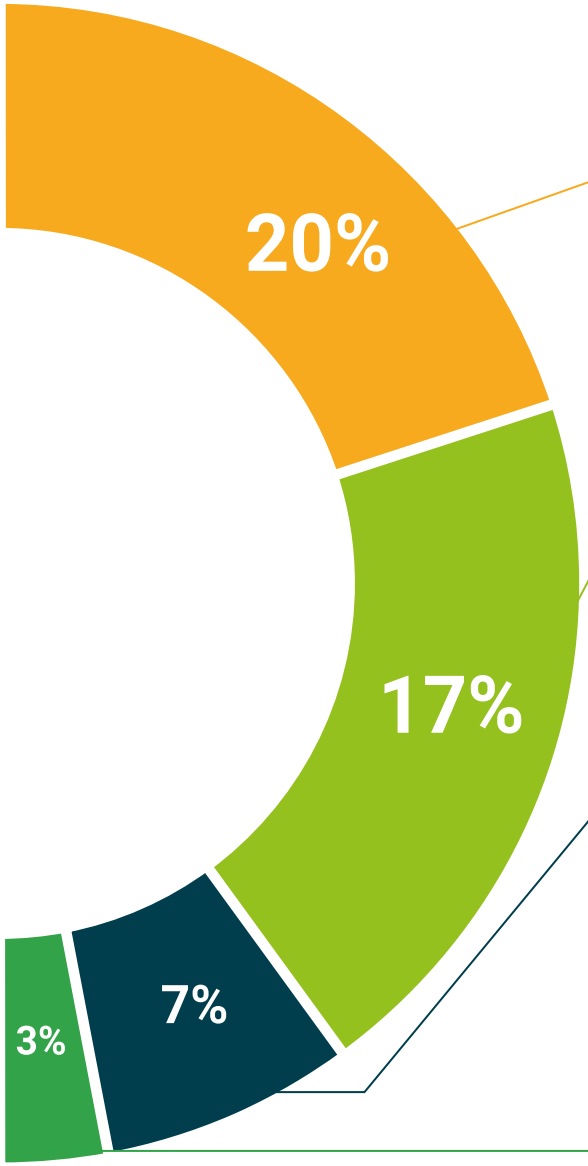
We present the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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

Additional Reading

Recent articles, consensus documents, international guides... In our virtual library you will have access to everything you need to complete your education.





Case Studies

Students will complete a selection of the best case studies in the field. Cases that are presented, analyzed, and supervised by the best specialists in the world.

Testing & Retesting

We periodically assess and re-assess your knowledge throughout the program. We do this on 3 of the 4 levels of Miller's Pyramid.

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 for 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

Teaching Staff

The teaching staff for this MBA is made up of a select group of international experts with extensive experience in the management and monitoring of Clinical Trials. Renowned professionals will contribute their up-to-date knowledge in key areas such as drug research and development, trial management and bioethical regulations. This high-level academic approach ensures practical specialization, preparing graduates to lead successfully in the field of clinical research.

The teaching team of this MBA is made up of true leaders in the Management and Monitoring of Clinical Trials for Nursing.

International Guest Director

Dr. Leslie K. Breitner, is an **internationally renowned specialist** with a distinguished career in the fields of **business administration,not-for-profit management, and health care**. Her professional and research career has focused on analyzing the impact of initiatives that improve the **quality of financial systems in healthcare organizations.**. In that sense, her main contributions have been related to **education and leadership**, collaborating with numerous educational institutions in the creation of training programs for managers.

She is also co-author of the popular accounting books *Essentials of Accounting, (10th Edition) and Essentials of Accounting Review*. *In these volumes, she reflects her extensive knowledge of* **financial management,budgeting and performance measurement in hospitals.**. In addition, many of the studies and contributions contained in her various publications have been supported by grants from the **U.S. Department of Health and Human Services.** .

Dr. Breitner is **a graduate** of **Boston University** and collaborates as a specialist at McGill University in Montreal, Canada. At McGill University, **she founded the International Master's Degree in Healthcare Leadership** (IMHL) program and served as **Academic Co-Director of the Graduate Program** in **Healthcare Management.** . She also lectures frequently at Harvard University, Washington University and Seton Hall University.

Dr. Breitner's professional experience has been recognized on numerous occasions, receiving awards from important organizations and university institutions around the world. Among other distinctions, she holds the **Beekhuis Award** from the Simmons College Graduate School of Management and is **an honorary member of the Boston chapter of the Beta Gamma Sigma Society**.

Dr. Breitner, Leslie

- Program Director, School of Healthcare Management, McGill University, Montreal, Canada
- Specialist in Hospitality Business Administration
- Director of the International Master's Degree in Healthcare Leadership
- Academic Co-Director of the Graduate Program in Health Care Management
- Supervisor of the Mitacs-Accelerate graduate research internship program
- Collaboration with UNICEF in Training on Budget and Fiscal Analysis
- Doctorate in Business Administration (DBA) from Boston University Graduate School of Management
- Master's Degree of Business Administration (MBA), Simmons College Graduate School of Management

Thanks to TECH you will be able to learn with the best professionals in the world"

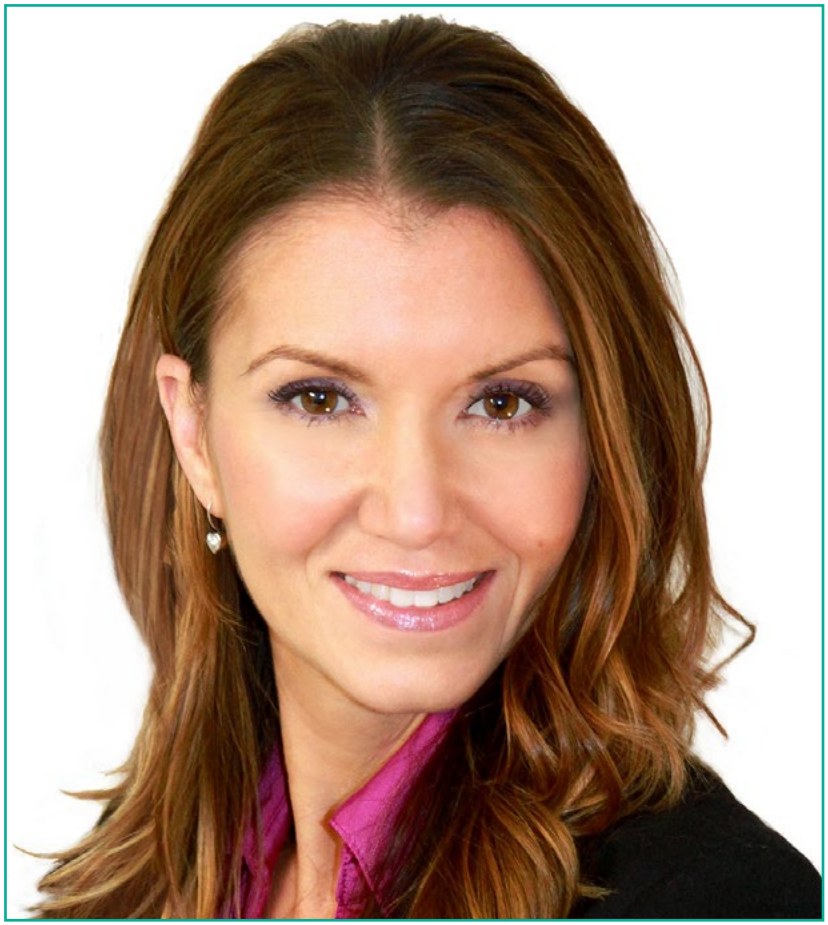
International Guest Director

With over 20 years of experience in designing and leading global **talent acquisition teams**, Jennifer Dove is an expert in **technology recruitment** and **strategy**. Throughout her career, she has held senior positions in several technology organizations within **Fortune 50**companies such as**NBCUniversal** and **Comcast**. Her track record has allowed her to excel in competitive, high-growth environments.

As **Vice President of Talent Acquisition** at **Mastercard**she is responsible for overseeing talent onboarding strategy and execution, collaborating with business leaders and **HR Managers** to meet operational and strategic hiring objectives. In particular, she aims to **build diverse**, **inclusive** and **high-perfoming teams** that drive innovation and growth of the company's products and services. In addition, she is adept at using tools to attract and retain the best people from around the world. She is also responsible for **amplifying** Mastercard's **employer brand** and **value proposition** through publications, events and social media.

Jennifer Dove has demonstrated her commitment to continuous professional development by actively participating in networks of **Human Resources** professionals and contributing to the onboarding of numerous employees at different companies. After earning her bachelor's degree in **Organizational Communication** from the University of **Miami**, she has held management positions in recruitment for companies in various areas.

On the other hand, it has been recognized for its ability to lead organizational transformations, **integrate technologies** into **recruitment processes** and develop leadership programs that prepare institutions for future challenges. She has also successfully implemented **wellness programs** that have significantly increased employee satisfaction and retention.



Ms. Dove, Jennifer

- Vice President of Talent Acquisition at Mastercard, New York, United States
- Director of Talent Acquisition at NBCUniversal Media, New York, USA
- Head of Recruitment at Comcast
- Director of Recruiting at Rite Hire Advisory, New York, United States
- Executive Vice President of the Sales Division at Ardor NY Real Estate
- Director of Recruitment at Valerie August & Associates
- Account Executive at BNC
- Account Executive at Vault
- Degree in Organizational Communication from the University of Miami

Thanks to TECH you will be able to learn with the best professionals in the world"

International Guest Director

A technology leader with decades of experience in **major technology multinationals**, Rick Gauthier has developed prominently in the field of **clouds** services **and** end-to-end process improvement. He has been recognized as a leader and manager of highly efficient teams, showing a natural talent for ensuring a high level of engagement among his employees.

He possesses innate gifts in strategy and executive innovation, developing new ideas and backing his success with quality data. His background at **Amazon** has allowed him to manage and integrate the company's IT services in the United States. At **Microsoft** he has led a team of 104 people, responsible for providing corporate-wide IT infrastructure and supporting product engineering departments across the company.

This experience has allowed him to stand out as a high-impact manager with remarkable abilities to increase efficiency, productivity and overall customer satisfaction.

Mr. Gauthier, Rick

- Regional IT Director at Amazon, Seattle, USA
- Senior Program Manager at Amazon
- Vice President of Wimmer Solutions
- Senior Director of Productive Engineering Services at Microsoft
- Degree in Cybersecurity from Western Governors University
- Technical Certificate in Commercial Diving from Divers Institute of Technology
- Degre in Environmental Studies from The Evergreen State College

Take this opportunity to learn about the latest advances in this field in order to apply it to your daily practice"

International Guest Director

Romi Arman is a renowned international expert with more than two decades of experience in **Digital Transformation**, **Marketing, Strategy** and **Consulting**. Through that extended trajectory, he has taken different risks and is a permanent **advocate** for **innovation** and **change** in the business environment. With that expertise, he has collaborated with CEOs and corporate organizations from all over the world, pushing them to move away from traditional business models. In this way, he has helped companies such as Shell Energy become **true market leaders,** focused on their **customers** and the **digital world.**

The strategies designed by Arman have a latent impact, as they have enabled several corporations **to improve the experiences of consumers, staff** and **shareholders** alike. The success of this expert is quantifiable through tangible metrics such as **CSAT**, **employee engagement** in the institutions where he has practiced and the growth of the **EBITDA financial indicator** in each of them.

Also, in his professional career, he has nurtured and **led high-performance teams** that have even received awards for their **transformational potential**. With Shell, specifically, the executive has always set out to overcome three challenges: meeting **customers**' complex **decarbonization** demands **supporting** a "**cost-effective decarbonization**" and **overhauling** a fragmented **data**, **digital and technology landscape**. As such, his efforts have shown that in order to achieve sustainable success, it is essential to start from the needs of consumers and lay the foundations for the transformation of processes, data, technology and culture.

In addition, the executive stands out for his mastery of the **business applications** of **Artificial Intelligence,** a subject in which he holds a postgraduate degree from the London Business School. At the same time, he has accumulated experience in **IoT** and **Salesforce.**

Mr. Arman, Romi

- Digital Transformation Director (CDO) at Shell Energy Corporation, London, United Kingdom
- Global Director of E-Commerce and Customer Service at Shell Energy Corporation
- National Key Account Manager (OEM and automotive retailers) for Shell in Kuala Lumpur, Malaysia
- Senior Management Consultant (Financial Services Sector) for Accenture based in Singapore
- Bachelor's Degree from the University of Leeds
- Postgraduate Degree in Business Applications of AI for Senior Executives from London Business School
- CCXP Customer Experience Professional Certification
- IMD Executive Digital Transformation Course

Do you want to update your knowledge with the highest educational quality? TECH offers you the most updated content in the academic market, designed by authentic experts of international prestige."

International Guest Director

Manuel Arens is an **experienced data management professional** and leader of a highly qualified team. In fact, Arens holds the position of **global purchasing manager** in Google's Technical Infrastructure and Data Center division, where he has spent most of his professional career. Based in Mountain View, California, he has provided solutions for the tech giant's operational challenges, such as master **data integrity, vendor data updates** and vendor **prioritization**. He has led data center supply chain planning and vendor risk assessment, generating improvements in vendor risk assessment, resulting in process improvements and workflow management that have resulted in significant cost savings.

With more than a decade of work providing digital solutions and leadership for companies in diverse industries, he has extensive experience in all aspects of strategic solution delivery, including **marketing, media analytics, measurement** and **attribution.** In fact, he has received a number of accolades for his work, including the **BIM Leadership Award**, the **Search Leadership Award**, the **Lead Generation Export Program Award** and the **Export Lead Generation Program Award and the EMEA Best Sales Model Award.**

Arens also served as **Sales Manager** in Dublin, Ireland. In this role, he built a team of 4 to 14 members over three years and led the sales team to achieve results and collaborate well with each other and cross-functional teams. He also served as **Senior Industry Analyst,** Hamburg, Germany, creating storylines for over 150 clients using internal and third party tools to support analysis. He developed and wrote in-depth reports to demonstrate his mastery of the subject matter, including understanding the **macroeconomic and political/ regulatory factors** affecting technology adoption and diffusion.

He has also led teams at companies such as Eaton, Airbus and Siemens, where he gained valuable account management and supply chain experience. He is particularly noted for continually exceeding expectations by **building valuable customer relationships** and **working seamlessly with people at all levels of an organization**, including stakeholders, management, team members and customers. His data-driven approach and ability to develop innovative and scalable solutions to industry challenges have made him a prominent leader in his field.

Mr. Arens, Manuel

- Global Procurement Manager at Google, Mountain View, United States
- Senior Manager, B2B Analytics and Technology, Google, United States
- Sales Director - Google, Ireland
- Senior Industry Analyst at Google, Germany
- Accounts Manager - Google, Ireland
- Accounts Payable at Eaton, United Kingdom
- Supply Chain Manager at Airbus, Germany

Bet on TECH! You will have access to the best teaching materials, at the forefront of technology and education, implemented by internationally renowned specialists in the field"

International Guest Director

Andrea La Sala is an **experienced Marketing executive** whose projects have had a **significant impact** on the **Fashion environment**. Throughout his successful career he has developed different tasks related to **Products**, **Merchandising** and **Communication**. All of this linked to with prestigious brands such as **Giorgio Armani**, **Dolce&Gabbana**, **Calvin Klein**, among others.

The results of this **high-profile international executive** have been linked to his proven ability to **synthesize information** in clear frameworks and execute **concrete actions** aligned to **specific business objectives**. In addition, he is recognized for his **proactivity** and **adaptability to fast-paced** work rhythms. To all this, this expert adds a **strong commercial awareness,, market vision** and a **genuine passion** for **products**.

As **Global Brand and Merchandising Director** at **Giorgio Armani**, he has overseen a variety of **Marketing strategies** for **apparel** and **accesories**. His tactics have also focused on the **retail environment** and **consumer needs** and **behavior**. From this position, La Sala has also been responsible for shaping the commercialization of products in different markets, acting as **team leader** in the **Design**, **Communication** and **Sales departments**..

On the other hand, in companies such as **Calvin Klein** or **Gruppo Coin**, he has undertaken projects to boost the **structure**, and **development** of **different collections**. He has been in charge of creating **effective calendars** for buying and selling **campaings.** He has also been in charge of the **terms**, **costs**, **processes** and **delivery times** of different operations.

These experiences have made Andrea La Sala one of the main and most qualified **corporate leaders** in **Fashion** and **Luxury**. A high managerial capacity with which he has managed to effectively **implement the positive positioning** of **different brands** and redefine their key performance indicators (KPIs).

Mr. La Sala, Andrea

- Global Brand & Merchandising Director Armani Exchange at Giorgio Armani, Milan, Italy
- Merchandising Director at Calvin Klein
- Brand Manager at Gruppo Coin
- Brand Manager at Dolce&Gabbana
- Brand Manager at Sergio Tacchini S.p.A.
- Market Analyst at Fastweb
- Graduate of Business and Economics at Università degli Studi del Piemonte Orientale

The most qualified and experienced professionals at international level are waiting for you at TECH to offer you a first class teaching, updated and based on the latest scientific evidence. What are you waiting for to enroll?"

International Guest Director

Mick Gram is synonymous with innovation and excellence in the field of **Business Intelligence** internationally. His successful career is linked to leadership positions in multinationals such as **Walmart** and **Red Bull.** Likewise, this expert stands out for his vision to **identify emerging technologies** that, in the long term, achieve an everlasting impact in the corporate environment.

On the other hand, the executive is considered a **pioneer** in the **use of data visualization techniques** that simplified complex sets, making them accessible and facilitating decision making. This ability became the pillar of his professional profile, transforming him into a desired asset for many organizations that bet on **gathering information** and **generating concrete actions** from them.

One of his most outstanding projects in recent years has been the **Walmart Data Cafe platform**, the largest of its kind in the world that is anchored in the **cloud** aimed at ***Big Data***analysis. In addition, he has held the position of **Director** of **Business Intelligence** at **Red Bull,** covering areas such as **Sales, Distribution, Marketing and Supply Chain Operations**. His team was recently recognized for its constant innovation regarding the use of Walmart Luminate's new API for Shopper and Channel insights.

As for his training, the executive has several Masters and postgraduate studies at prestigious centers such as the **University of Berkeley,**in the United States, and the **University of Copenhagen**, in Denmark. Through this continuous updating, the expert has attained cutting-edge competencies. Thereby, he has come to be considered a **born leader** of the **new global economy**, centered on the drive for data and its infinite possibilities.

Mr. Gram, Mick

- Director of Business Intelligence and Analytics at Red Bull, Los Angeles, United States
- Business Intelligence Solutions Architect for Walmart Data Cafe
- Independent Business Intelligence and Data Science Consultant
- Director of Business Intelligence at Capgemini
- Senior Analyst at Nordea
- Senior Business Intelligence Consultant at SAS
- Executive Education in AI and Machine Learning at UC Berkeley College of Engineering
- Executive MBA in e-commerce at the University of Copenhagen
- B.Sc. and M.Sc. in Mathematics and Statistics at the University of Copenhagen

Study at the world's best online university according to Forbes! In this MBA you will have access to an extensive library of multimedia resources, developed by internationally renowned professors"

International Guest Director

Scott Stevenson is a distinguished expert in the **Digital Marketing** sector who, for more than 19 years, has been linked to one of the most powerful companies in the entertainment industry, **Warner Bros. Discovery.** In this role, he has played a fundamental role in **overseeing logistics** and **creative workflows** across various digital platforms, including social media, search, display and linear media.

This executive's leadership has been crucial in driving in **production strategies** in **paid media**, resulting in a **marked improvement** which has resulted in **company's conversion** rates. At the same time, he has assumed other roles, such as Director of Marketing Services and Traffic Manager at the same multinational during his former management.

Stevenson has also been involved in the global distribution of video games and **digital property campaigns**. He was also responsible for introducing operational strategies related to the formation, completion and delivery of sound and image content for **television commercials** and ***trailers***.

In addition, he holds a Bachelor's degree in Telecommunications from the University of Florida and a Master's Degree in Creative Writing from the University of California, which demonstrates his proficiency in **communication** and **storytelling.**. In addition, he has participated at Harvard University's School of Professional Development in cutting-edge programs on the use of **Artificial Intelligence** in **business.**. Therefore, his professional profile stands as one of the most relevant in the current field of **Marketing** and **Digital Media.**

Mr. Stevenson, Scott

- Director of Digital Marketing at Warner Bros. Discovery, Burbank, United States
- Traffic Manager at Warner Bros. Entertainment.
- Master's Degree in Creative Writing from the University of California
- Bachelor's Degree in Telecommunications from the University of Florida

Achieve your academic and career goals with the best qualified experts in the world! The faculty of this MBA will guide you through the entire learning process"

International Guest Director

Awarded with the "International Content Marketing Awards" for her creativity, leadership and quality of her informative contents, Wendy Thole-Muir is a recognized **Communication Director** highly specialized in the field of **Reputation Management.**

In this sense, she has developed a solid professional career of more than two decades in this field, which has led her to be part of prestigious international reference entities such as **Coca-Cola**. Her role involves the supervision and management of corporate communication, as well as the control of the organizational image. Among her main contributions, she has led the implementation of the Yammer **internal interaction platform**. Thanks to this, employees increased their commitment to the brand and created a community that significantly improved the transmission of information.

On the other hand, she has been in charge of managing the communication of the companies' **strategic investments** in different African countries. An example of this is that she has managed dialogues around significant investments in Kenya, demonstrating the commitment of the entities to the economic and social development of the country. At the same time, she has achieved numerous **recognitions** for her ability to manage the perception of the firms in all the markets in which it operates. In this way, she has ensured that companies maintain a high profile and consumers associate them with high quality.

In addition, in her firm commitment to excellence, she has actively participated in renowned global **Congresses and Symposiums** with the objective of helping information professionals to stay at the forefront of the most sophisticated techniques to **develop successful strategic communication plans**. In this way, she has helped numerous experts to anticipate institutional crisis situations and to manage adverse events in an effective manner.

Ms. Thole-Muir, Wendy

- Director of Strategic Communications and Corporate Reputation at Coca-Cola, South Africa
- Head of Corporate Reputation and Communications at ABI at SABMiller de Lovania, Belgium
- Communications Consultant at ABI, Belgium
- Reputation and Communications Consultant at Third Door in Gauteng, South Africa
- Master's Degree in Social Behavioral Studies, University of South Africa
- Master's Degree in Sociology and Psychology, University of South Africa
- Bachelor's Degree in Political Science and Industrial Sociology from the University of KwaZulu-Natal
- Bachelor's Degree in Psychology from the University of South Africa

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Management

Dr. Gallego Lago, Vicente

- Military pharmacist at HMC Gómez Ulla
- Doctor of Pharmacy
- Bachelor's Degree in Pharmacy from the Complutense University of Madrid
- Specialty in Pharmacy in the Pharmacy Service of the Hospital 12 de Octubre.

Professors

Dr. Valtueña Murillo, Andrea

- Pharmacovigilance Technician at Tecnimede Group
- Quality, Regulation and Pharmacovigilance Technician at Cantabria Labs. Medical Nutrition
- Pharmacy Technician in José Carlos Montilla Pharmacy
- Professional Master's Degree in Pharmaceutical and Parapharmaceutical Industry in CESIF
- Degree in Pharmacy at Complutense University of Madrid

Ms. Pérez Ingidua, Carla

- Research Nurse at the Clinical Pharmacology Service of the San Carlos Clinical Hospital
- PhD in Nursing from the Complutense University of Madrid.
- Nurse Coordinator of Phase I research studies in Oncology at The START Center for Cancer Care
- Hospitalization Nurse in the Obstetrics Service of SERMAS
- Master's Degree in Health Care Research from the Complutense University of Madrid
- Degree in Nursing from the Complutense University of Madrid

Ms. Santacreu Guerrero, Mireia

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

Dr. Dompablo Tobar, Mónica

- Researcher at the Psychiatry Department of the Hospital Universitario 12 de Octubre.
- Doctorate in Psychology the Complutense University of Madrid.
- Bachelor's Degree in Psychology from the Autonomous University of Madrid.
- Official Master's Degree in Initiation to Research in Mental Health by the Complutense University of Madrid.
- Official Master's Degree in Research-Documentation, Carlos III University of Madrid University

D. Bravo Ortega, Carlos

- Clinical Trials Coordinator in the Clinical Nephrology Service of the 12 de Octubre Hospital
- Specialist in Clinical Trials and Laboratory Techniques.
- 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. Gómez Abecia, Sara

- Coordinator of oncology studies at the 12 de Octubre Hospital.
- Graduate in Biological Sciences from the Complutense University of Madrid.
- Professional Master's Degree in Clinical Trial Monitoring by ESAME Foundation.
- Title of Project Management in Clinical Research by CESIV

Ms. Ochoa Parra, Nuria

- Coordinator of clinical studies in the Cardiology Department of the 12 de Octubre University Hospital.
- Graduate in Pharmacy from the Complutense University of Madrid.
- Master's Degree in Clinical Trials from the University of Seville
- Course on Systematic Reviews and meta-analysis by the Madrid Regional Ministry of Health
- Course on Good Practices in Clinical Research by the Madrid Regional Ministry of Health

Mr. Moreno Muñoz, Guillermo

- Specialist in Pharmacology and Monitoring of Clinical Trials
- 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. Benito Zafra, Ana

- Biologist specializing in Biochemistry, Molecular Biology and Biomedicine.
- Coordinator of Trials and Clinical Projects in the Heart Failure Unit of the Cardiology Department of the 12 de Octubre Hospital.
- 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. 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

- Principal Investigator at CIBERSAM
- Principal Investigator at the Center for Biomedical Research in the Mental Health Network.
- Principal Investigator in the Cognition and Psychosis Group at Hospital 12 de Octubre.
- Head of section of the inpatient unit and day hospital at Hospital 12 de Octubre.
- Specialist in Psychiatry in INSALUD
- PhD in Psychiatry, Autonomous University of Madrid.
- Bachelor's Degree in Medicine and Surgery from the Autonomous University of Madrid
- Degree in Psychology from the UNED
- Master's Degree in Psychotherapy from the Autonomous University of Madrid.
- Specialist in Alcoholism, Autonomous University of Madrid.

Ms. Bermejo Plaza, Laura

- Clinical Trials Coordinator at the HIV Unit of the 12 de Octubre University Hospital.
- Specialist in Clinical Trials and Laboratory Techniques.
- Operating Room Nurse at the Martha María Hospital.
- Degree in Nursing from the Complutense University of Madrid

Ms. Jiménez Fernández, Paloma

- Coordination of Clinical Trials Senior IQVIA
- Coordinator of clinical trials in the Rheumatology Service of the 12 de Octubre Hospital
- Clinical Trial Monitor at the Inflammatory Bowel Disease Research Unit at La Princesa Hospital.
- Graduate in Pharmacy from the Complutense University of Madrid.
- Master's Degree in Clinical Trials Monitoring and Management from the Autonomous University of Madrid

Dr. Onteniente Gomis, María del Mar

- Clinical Trials Coordinator at the Dermatology Unit of the 12 de Octubre Hospital
- Veterinarian in the veterinary clinics Vista Alegre, Campos de Nijar and San Francisco.
- Degree in Veterinary Medicine from the University of Córdoba
- Master's Degree in Clinical Trials from the University of Sevilla

Ms. Martín-Arriscado Arroba, Cristina

- Specialist in Biostatistics at Hospital 12 de Octubre.
- Member of the Drug Research Ethics Committee (CEIm) of the 12 de Octubre Hospital.
- Graduate in Applied Statistics from the Complutense University of Madrid.
- Diploma in Statistics from the Complutense University
- Master's Degree in Biostatistics from the Complutense University

Ms. De Torres Pérez, Diana

- Clinical researcher at Premier Research
- Trials Coordinator at the Cardiology Service (Hemodynamics and Arrhythmias) of the 12 de Octubre University Hospital
- Degree in Pharmacy from the Complutense University of Madrid
- Master's Degree in Coordination of Clinical Trials at ESAME
- Master's Degree in Study Coordinator in ESAME Pharmaceutical- Business School

Ms. Cano Armenteros, Montserrat

- Research Project Coordinator
- Coordinator of research studies at 12 de Octubre University Hospital
- Vaccine and Infection Studies Coordinator at CSISP-Salud Publica
- Clinical Research Assistant at TFS HealthScience
- Lecturer in postgraduate university studies
- Degree in Biology by the University of Alicante
- Master's Degree in Clinical Trials from the University of Sevilla
- Master's Degree in Clinical Analysis from the University CEU Cardenal Herrera
- Master's Degree in Primary Care Research from the Miguel Hernández University of Elche

Mr. Sánchez Ostos, Manuel

- Coordinator of Clinical Trials in IMIBIC
- Data Manager at Institute Maimonides Biomed Research Córdoba (IMIBIC)
- Research Support Technician at the University of Córdoba
- Degree in Biology from the University of Córdoba
- Master's Degree in Clinical Trial Monitoring and Pharmaceutical Development from the University of Nebrija in Madrid
- Master's Degree in Biotechnology from the University of Córdoba
- Master's Degree in Teacher Training from the University of Córdoba

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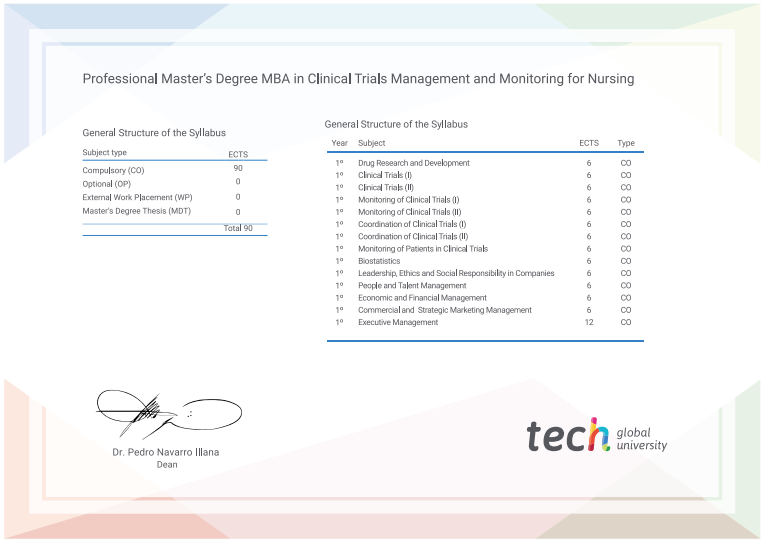

Professional Master's Degree MBA in Clinical Trials Management and Monitoring for Nursing

General Structure of the Syllabus

Subject type	ECTS
Compulsory (CO)	90
Optional (OP)	0
External Work Placement (WP)	0
Master's Degree Thesis (MDT)	0
	Total 90

General Structure of the Syllabus

Year	Subject	ECTS	Type
1º	Drug Research and Development	6	CO
1º	Clinical Trials (I)	6	CO
1º	Clinical Trials (II)	6	CO
1º	Monitoring of Clinical Trials (I)	6	CO
1º	Monitoring of Clinical Trials (II)	6	CO
1º	Coordination of Clinical Trials (I)	6	CO
1º	Coordination of Clinical Trials (II)	6	CO
1º	Monitoring of Patients in Clinical Trials	6	CO
1º	Biostatistics	6	CO
1º	Leadership, Ethics and Social Responsibility in Companies	6	CO
1º	People and Talent Management	6	CO
1º	Economic and Financial Management	6	CO
1º	Commercial and Strategic Marketing Management	6	CO
1º	Executive Management	12	CO

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