Hybrid Professional Master's Degree

MBA Management and Monitoring of Clinical Trials

tech technological university

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MBA Management and Monitoring of Clinical Trials

Course Modality: **Hybrid (Online + Clinical Internship)**
Duration: **12 months.**
Certificate: **TECH Technological University**
Teaching Hours: **1,620 hours.**
Website: www.techtitute.com/pk/medicine/hybrid-professional-master-degree/hybrid-professional-master-degree-mba-management-monitoring-clinical-trials

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01

Introduction

Research in the health area acquires a relevant role due to its power to improve people's health and quality of life. For this reason, more and more investments are being made in clinical trials to demonstrate the effectiveness of a given drug or therapy. In recent times, with the health crisis caused by the COVID, it has demonstrated more than ever its importance and, therefore, professionals who are up to date in this area are required. Thanks to this program, doctors will update their knowledge to conduct this type of trials, thanks to the best theoretical content of the moment and a practical stay of 3 weeks with which they will be able to learn from the hand of the main specialists in the field.

The development of new drugs is essential to mitigate the effects of resistant diseases. Update yourself in this field and get your research to acquire the necessary effectiveness to introduce new drugs in the market"

The emergence of new diseases and the resistance of many of them to drugs force physicians to be constantly researching new formulations that demonstrate the necessary viability to be able to introduce them on the market. The most recent example, which has gone around the world, has been the launch, after months of intensive work by scientists from all over the world, of the vaccines needed to mitigate the effects of COVID-19 infection. Undoubtedly, this has highlighted the need for greater investment in research, but it has also demonstrated the great value and quality of researchers around the world.

Nowadays, there are many healthcare professionals who decide to broaden their capabilities in the area of research, opting to continue their studies to enter a sector that demands specialized professionals with the ability to adapt and the appropriate handling of the most innovative technology in this field.

To this end, TECH offers a Hybrid Professional Master's Degree MBA in Management and Monitoring of Clinical Trials, thanks to which specialists will be able to gain in-depth knowledge of the entire research process for new drugs, the specific regulations of the sector, the monitoring of patients who undergo this type of trial or the coordination of these processes.

This program will undoubtedly mark a before and after in their training and will enhance their competencies to lead successful research teams, which will become the scientific elite in healthcare. And all this will be possible thanks to the multiple advantages of this Hybrid Professional Master's Degree: the most up-to-date theoretical content, the best teaching methodology and a 100% online format that allows you to self-manage the pace at which you update your knowledge.

In addition, medical professionals, upon completing the program, will have access to a 3-week internship at a leading hospital center, where they will be able to work alongside leading experts in the field, learning the ins and outs of the profession and developing the necessary skills to manage their work in the most recognized teams in the field of clinical trials.

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

- The development of more than 100 clinical cases presented by professionals in Clinical Trial Management and Monitoring
- Their graphic, schematic and eminently practical contents provide scientific and assistance information on those medical disciplines that are essential for professional practice
- The presentation of practical workshops on Clinical Trials
- An algorithm-based interactive learning system for decision-making in the clinical situations presented throughout the course
- Practical guidelines on how to approach Clinical Trials
- Its special emphasis on evidence-based medicine and research methodologies for conducting clinical trials
- Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- Content that is accessible from any fixed or portable device with an Internet connection
- A clinical internship in one of the best hospitals in the world

Take an intensive 3-week program at a prestigious center, which will bring you up to date with the latest techniques used in the development of new drugs"

Access simulated environments with this program to achieve a level of competence that will enable you to enhance your ability to successfully manage clinical trial teams.

In just 12 months you will be able to expand your skills and competencies in the field of new drug research and biostatistics.

In this proposed Hybrid Professional Master's Degree, of a professional nature and blended learning modality, the program is aimed at updating medical professionals who perform their functions in research centers, and who require a high level of qualification. The contents are based on the latest scientific evidence, and oriented in a didactic way to integrate theoretical knowledge into the practice of the MBA in Clinical Trial Management and Monitoring, and the theoretical and practical elements will facilitate the updating of knowledge and allow decision making.

Thanks to their multimedia content developed with the latest educational technology, they will allow medical professional a situated and contextual learning, that is, a simulated environment that will provide an immersive learning programmed to train in real situations. The design of this program is focused on Problem-Based Learning, by means of which the student must try to solve the different professional practice situations that arise during the program. For this purpose, the student will be assisted by an innovative interactive video system created by renowned experts.

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Why Study this Hybrid Professional Master's Degree?

The current great importance of Clinical Trials has opened the doors to a complex and promising panorama for professionals oriented to this area. Because of this, more and more trials are being carried out in an attempt to respond to the numerous current health challenges in terms of viruses, bacteria and all types of pathologies affecting human beings. However, most of the academic programs oriented to this discipline have an eminently theoretical and rigid orientation, without taking into account the needs of the professional. For this reason, TECH has designed this program, which combines online learning with a 100% practical stay in a prestigious center in the field of research.

TECH provides you with a unique opportunity: a practical and intensive 3-week internship in a renowned center in the field of clinical research"

1. Updating from the latest technology available

The new paradigms of the research world have made their way by incorporating state-of-the-art technology in the various processes of a clinical trial. So, with this program, the professional will have access to the latest equipment, present in the prestigious centers that TECH has selected to carry out these intensive internships.

2. Gaining In-Depth Knowledge from the Experience of Top Specialists

The enormous complexity of the current Clinical Trials requires a constant orientation that brings the professional up to date with these processes. For this reason, throughout the internship offered by TECH, the student will be accompanied by a large team of professionals, who will ensure the proper development of the stay, and who will transmit directly the latest advances in the discipline.

3. Entering First-Class Clinical Environments

Only TECH provides access to prestigious clinical environments. That is precisely what the student will find here: the opportunity to carry out an internship in a renowned center in the area of Clinical Trials. In this way, you will be able to observe and participate in the day-to-day work of a high-level team, which will always apply the highest quality standards to its daily work.

4. Combining the Best Theory with State-of-the-Art Practice

Most academic options in the area of Clinical Trials have a completely theoretical and not very dynamic perspective. In addition, they often impose rigid schedules that complicate the possibility of combining studies with personal and professional life. However, this TECH program combines flexible, online learning with an intensive stay at a prestigious center, where you can put into practice the latest advances in this complex and exciting healthcare discipline.

5. Expanding the Boundaries of Knowledge

The professional will be able to expand their horizons by keeping up to date with specialists of international prestige. In this way, this program is not limited to offering an education that is fully adapted to current clinical needs, but also provides students with the possibility of working in highly reputable global environments, with the opportunity to establish networking networks with other specialists.

You will have full practical immersion at the center of your choice"

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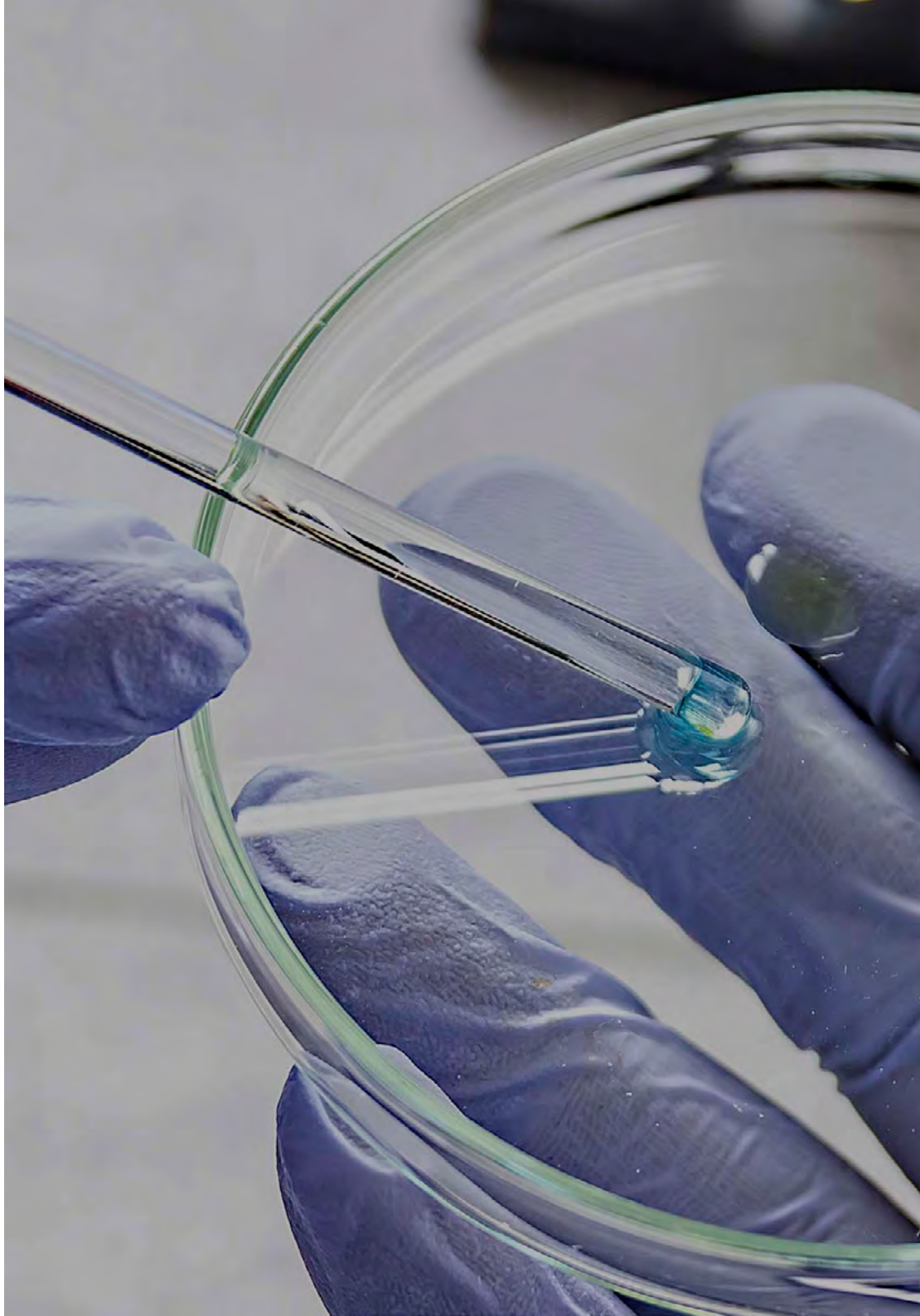
Objectives

The completion of this Hybrid Professional Master's Degree MBA in Clinical Trial Management and Monitoring at TECH is a unique opportunity for medical professionals who wish to keep abreast of the latest developments in the field of research. In this way, they will gain access to specialized knowledge thanks to which they will be able to develop the technical and leadership skills to manage teams and projects that achieve success at the healthcare level, thus bringing significant benefits to the public.

With TECH you will be up to date on the specific protocols for Clinical Trials, allowing you to act with greater safety in each process"

General Objective

- This Hybrid Professional Master's Degree will provide physicians with significant advantages in terms of competence, since they will develop the skills required for the successful research of new drugs. In this way, they will be updated on the progress achieved in the follow-up of the entire Clinical Trial, its control and monitoring of each phase. They will also expand their ability to analyze the data and reach scientific conclusions that determine the success or failure of the trial, being able to convey the results faithfully and using the most appropriate terms in their field



Specific Objectives

Module 1. Drug research and development

- Explain the pharmacokinetic processes that a drug undergoes in the organism
- Identify the legislation that regulates each of the steps in the development and authorization of a drug
- Define the specific regulation of some drugs (biosimilars, advanced therapies)
- Define the use in special situations and their types
- Examine the process of financing a drug
- Specify strategies for the dissemination of research results
- Present how to read scientific information critically
- Compile sources of information on drugs and their types

Module 2. Clinical Trials I

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

Module 3. Clinical Trials II

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

Module 4. Bioethics and regulations

- Substantiate the justification of bioethics in the field of research
- Establish the application of ethical principles in the selection of participants
- Specify the principles of the benefit-risk balance in research with drugs and medical devices
- Define informed consent and patient information sheet
- Analyze the guarantees of patient safety in clinical trials
- Establish procedures for the authorization of drugs and medical devices
- Presentar la función y estructura de los comités de ética de investigación clínica

Module 5. Monitoring of Clinical Trials I

- Specify both the professional profile of the clinical trial monitor and the skills that must be developed to carry out the monitoring process of a clinical trial
- Establish your responsibility in the selection of the center and in the initiation of the study
- Generate knowledge on the practical aspects of the visits prior to the start of the Clinical Trial
- Present the basis for the essential documentation for the implementation of the clinical trial at the center
- Prepare the student in the correct handling of a pre-selection visit and initiation in the research center
- Assess the involvement of the Hospital Pharmacy Service in the management, control and traceability of the medication in the study
- Appreciate the importance of maintaining good communication between team members involved in the development of a clinical trial

Module 6. Monitoring of Clinical Trials II

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

Module 7. Coordination of Clinical Trials I

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

Module 8. Coordination of Clinical Trials II

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

Module 9. Follow-up of Patients in Clinical Trials

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

Module 10. Biostatistics

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

Apply the most effective mathematical criteria in your clinical trials and arrive at more reliable results"

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Skills

Specialists who pass the evaluations of this Hybrid Professional Master's Degree in TECH will be able to enhance their skills in the management of research teams that focus their studies on clinical trials. Because of this, they will be able to participate in this type of process, contributing all their knowledge and following the highest safety criteria, both for the trials themselves and for the health of patients. In this way, you will broaden your skills to become part of the teams of major national and international pharmaceutical companies.

This program enhances your ability to lead research projects aimed at creating new drugs that are effective against resistant diseases"

General Skills

- Develop all phases of a clinical trial
- Monitor patients participating in research projects
- Carry out the whole process of the Clinical Trials following the current legislation in the matter
- Perform process monitoring

Expand your skills in communicating clinical trial results through the most effective means with this university program"

Specific Skills

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

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Course Management

TECH has assembled an excellent teaching team, composed of professionals with extensive experience in research in Medicine, Pharmacy, Psychiatry in reference hospitals. Their extensive knowledge in this field is evident in the advanced syllabus of this program. Likewise, its proximity will allow the specialist to consult any doubts that may arise about the content during the course of this Hybrid Professional Master's Degree.

TECH has rigorously selected the teaching team specialized in research and clinical trials, which teaches this program"

Management

Dr. Vicente Gallego Lago

- Military pharmacist at HMC Gómez Ulla
- Doctor of Pharmacy
- Degree in Pharmacy from the Complutense University of Madrid
- Specialist in Pharmacy, Pharmacy Department, 12 de Octubre Hospital

Professors

Ms. Marta Díaz García

- Nurse of Pulmonology, 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

Mr. Guillermo Moreno Muñoz

- 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)

Dr. Andrea Valtueña Murillo

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

Dr. Roberto Rodríguez Jiménez

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

Dr. Mónica Dompablo Tobar

- Researcher at the Psychiatry Department of the 12 de Octubre University Hospital
- Doctorate in Psychology the Complutense University of Madrid
- Degree in Psychology from the Universidad Autónoma de Madrid
- Interuniversity Master's Degree in Initiation to Research in Mental Health at the Complutense University of Madrid
- Master's Degree in Research-Documentation from the Universidad Carlos III de Madrid

Ms. Carla Pérez Indigua
- Research Nurse in the Clinical Pharmacology Service of the San Carlos Clinical Hospital
- Nurse Coordinator of Phase I research studies in Oncology at The START Center for Cancer Care
- Hospitalization Nurse of the Obstetrics Service of SERMAS
- Professor of the subject "Ethics of human research" at UCM
- Dr. in Nursing from the Complutense University of Madrid
- Degree in Nursing from the Complutense University of Madrid
- Master's Degree in Research Methodology in Health Care from the UCM

Ms. Laura Bermejo Plaza
- Coordinator of Clinical Trials at the HIV Unit of the 12 de Octubre University Hospital of Madrid
- 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. Nuria Ochoa Parra
- Clinical Studies Coordinator in the Cardiology Service of the Universitario12 of de Octubre Hospital
- Graduate in Pharmacy from the Complutense University of Madrid
- Master's Degree in Clinical Trials from the University of Seville
- Program on Systematic Reviews and meta-analysis by the Madrid Regional Ministry of Health
- Program on Good Practices in Clinical Research by the Madrid Regional Health Ministry

Ms. Paloma Jiménez Fernández
- Coordination of Clinical Trials Senior IQVIA
- Clinical Trials Coordinator in the Rheumatology Service of the 12 de Octubre Hospital
- Clinical Trials 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 Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

Dr. María del Mar Onteniente Gomis
- Coordinator of Clinical Trials in the Dermatology Service of the 12 de from Octubre Hospital
- Veterinary 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 Seville

Ms. Cristina Martín-Arriscado Arroba
- Specialist in Biostatistics at the Hospital 12 de Octubre
- Member of the Ethics Committee for Research with Medicines (Drug Research Ethics Committee (CEIM)) of the Hospital 12 de Octubre
- Graduate's Degree in Applied Statistics by the University Complutense
- Postgraduate Certificate in Statistics from the Complutense University
- Master's Degree in Pediatric Biostatistics, Complutense University

Ms. Ana Benito Zafra
- Biologist Specialist in Biochemistry, Molecular Biology and Biomedicine
- Coordinator of clinical trials and projects in the Heart Failure Unit at 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. Diana De Torres Pérez
- Clinical Researcher at Premier Research
- Coordinator of Trials in 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. Mireia Santacreu Guerrero
- 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

Mr. Carlos Bravo Ortega
- 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. Sara Gómez Abecia
- Coordinator of oncology studies at Hospital 12 de Octubre
- Graduate in Biological Sciences from the Complutense University of Madrid
- Master's Degree in Monitoring of Clinical Trials from the ESAME Foundation
- Project Management in Clinical Research program by CESIV

Ms. Montserrat Cano Armenteros
- Coordinator of research studies at the 12 de Octubre University Hospital
- Coordinator of vaccine and infection studies at CSISP-Salud Pública
- Clinical Research Assistant at TFS HealthScience
- University postgraduate studies teacher
- Degree in Biology from the University of Alicante
- Master's Degree in Clinical Trials from the University of Seville
- Master's Degree in Clinical Analysis at CEU Cardenal Herrera University
- Master's Degree in Primary Care Research from the Miguel Hernández University of Elche

Mr. Manuel Sánchez Ostos
- Coordination of Clinical Trials in IMIBIC
- Data Manager at Institute Maimonides Biomed Research Cordoba (IMIBIC)
- Research Support Technician at the University of Cordoba
- Grade in Biology from the University of Córdoba
- Master's Degree in Clinical Trial Monitoring and Pharmaceutical Development, Nebrija University (Madrid)
- Master's Degree in Biotechnology from the University of Cordoba
- Master's Degree in Teacher Training, University of Córdoba

06

Educational Plan

The syllabus of this Hybrid Professional Master's Degree has been designed with the needs of medical professionals in mind, who must be up to date in the Management and Monitoring of Clinical Trials. For this purpose, this academic institution offers a very complete syllabus ranging from the development of new drugs to bioethics and biostatistics, patient follow-up and trial coordination. In this way, through a fully online theoretical study, the professional will obtain the latest scientific information to lead research projects.

Enter into a high-level teaching, with a theoretical-practical and current approach on the Management and Monitoring of Clinical Trials"

Module 1. Drug research and development

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

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

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

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

1.5. Regulation of Drugs for Human Use
- 1.5.1. Introduction
- 1.5.2. Authorization Procedures
- 1.5.3. How is a Drug Evaluated? Authorization File
- 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 Purpose
- 2.3.2. Clinical Trials According to the Scope of Research
- 2.3.3. Clinical Trials Methodology
- 2.3.4. Treatment Groups
- 2.3.5. Clinical Trials Masking
- 2.3.6. Treatment Assignment

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

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

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

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

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

3.2. Involvement of the Pharmacy Service in the Realization of Clinical Trials Sample Management II
- 3.2.1. Preparation/Conditioning
  - 3.2.1.1. Introduction
  - 3.2.1.2. Exposure Routes and Handler Protection
  - 3.2.1.4. Centralized Preparation Unit
  - 3.2.1.5. Facilities
  - 3.2.1.6. Individual Protection Equipment
  - 3.2.1.7. Closed Systems and Handling Equipment
  - 3.2.1.8. Technical Aspects of Preparation
  - 3.2.1.9. Cleaning Standards
  - 3.2.1.10. Waste Treatment in the Preparation Area
  - 3.2.1.11. Actions in Case of Spill and/or Accidental Exposure
- 3.2.2. Accounting/Inventory
- 3.2.3. Return/Destruction
- 3.2.4. Reports and Statistics

3.3. Involvement of the Pharmacy Service in the Realization of Clinical Trials Role of the Pharmacist
- 3.3.1. Visits Manager
  - 3.3.1.1. Preselection Visit
  - 3.3.1.2. Initiation Visit
  - 3.3.1.3. Monitoring Visit
  - 3.3.1.4. Audits and Inspections
  - 3.3.1.5. Closing Visit
  - 3.3.1.6. Archive
- 3.3.2. Member of the Ethics Committee
- 3.3.3. Clinical-Research Activity
- 3.3.4. Teaching Activity
- 3.3.5. Process Auditor
- 3.3.6. Complexity of CTs
- 3.3.7. CTs as Sustainability the Health Care System

3.4. Clinical Trials in the Hospital Urology Service I
- 3.4.1. Basic Principles of Urologic Pathology Related to Clinical Trials
  - 3.4.1.1. Non-Oncologic Urologic Pathology
    - 3.4.1.1.1. Benign Prostatic Hypertrophy
    - 3.4.1.1.2. Urinary Infection
    - 3.4.1.1.3. Erectile Dysfunction
    - 3.4.1.1.4. Hypogonadism.
  - 3.4.1.2. Oncologic Urologic Pathology
    - 3.4.1.2.1. Bladder Tumors
    - 3.4.1.2.2. Prostate Cancer
- 3.4.2. Background and Rationale for Clinical Trials in Urology
  - 3.4.2.1. Foundation
  - 3.4.2.2. Background
  - 3.4.2.3. Placebo Rationale
  - 3.4.2.4. Name and Mechanism of Action of the Investigational Product
  - 3.4.2.5. Conclusions from Previous Studies in Humans
  - 3.4.2.6. Benefits and Risks of Study Medication
    - 3.4.2.6.1. Dosage and Administration
    - 3.4.2.6.2. Medication Management Guidelines at Home
    - 3.4.2.6.3. Overdosage/Infradosification
  - 3.4.2.7. Double-Blind/Open Study
- 3.4.3. Objectives and Assessment Criteria of the Study
  - 3.4.3.1. Study Objectives
    - 3.4.3.1.1. Safety Objective
    - 3.4.3.1.2. Exploratory Objectives
  - 3.4.3.2. Assessment Criteria of the Study
    - 3.4.3.2.1. Main Efficacy Assessment Criteria
    - 3.4.3.2.2. Secondary Efficacy Assessment Criteria
- 3.4.4. Research Plan
- 3.4.5. Preselection of Candidates for Clinical Trials
- 3.4.6. Study Procedures by Period

3.5. Clinical Trials in the Urology Service II
- 3.5.1. Patient Retention
  - 3.5.1.1. Post-Treatment Monitoring Visits
  - 3.5.1.2. Long-term Monitoring Visits
- 3.5.2. Safety Assessments
  - 3.5.2.1. Adverse Effects Management
  - 3.5.2.2. SAEs Management
  - 3.5.2.3. Assigned Treatment Emergency Unblinding
- 3.5.3. Study Administration
  - 3.5.3.1. Dose-Limiting Toxicities
  - 3.5.3.2. Interrupting the Treatment
  - 3.5.3.3 Regulatory Compliance and Ethics
  - 3.5.3.4. Informed Consent
- 3.5.5. Quality Control and Compliance
  - 3.5.5.1. Authorization of Subjects Protected Health Information
  - 3.5.5.2. Retention of Study Records and Files
  - 3.5.5.3. Data Collection Notebooks
  - 3.5.5.4. Protocol Amendments
- 3.5.6. Conclusions

3.6. Approval of a Clinical Trial to the Urology Service Steps to Follow Trial Conclusion
- 3.6.1. Feasibility
- 3.6.2. Preselection Visit
  - 3.6.2.1. Main Investigators Role
  - 3.6.2.2. Logistics and Hospital Resources
- 3.6.3. Documentation
- 3.6.4. Initiation Visit
- 3.6.5. Source Document
  - 3.6.5.1. Patient's Clinical History
  - 3.6.5.2. Hospital Reports
- 3.6.6. Vendors
  - 3.6.6.1. Interactive Web Response Systems (IWRS)
  - 3.6.6.2. Electronic Case Report Form (eCRF)
  - 3.6.6.3. Images
  - 3.6.6.4. Suspected Unexpected Serious Adverse Reactions (SUSARs)
  - 3.6.6.5. Accounting
- 3.6.7. Education
- 3.6.8. Delegation of Functions
- 3.6.9. Visit to Other Services Involved
- 3.5.10. Closing the Trial

3.7. General Information about Clinical Trials in Children and Adolescents
- 3.7.1. History of Clinical Trials in Children
- 3.7.2. Informed Consent

3.8. Clinical Trials in Adolescents
- 3.8.1. Adolescent Clinical Trials Practical Features
- 3.8.2. New Approaches to Adolescent Trials

3.9. Clinical Trials in Children
- 3.9.1. Specific Physiological Characteristics of the Child
- 3.9.2. Children Clinical Trials

3.10. Clinical Trials in Neonatal
- 3.10.1. Specific Physiological Characteristics the Neonatal
- 3.10.2. Neonatal Clinical Trials

Module 4. Bioethics and regulations

4.1. Basic Ethical Principles and Most Relevant Ethical Norms
- 4.1.1. Aims of Biomedical Science
- 4.1.2. Rights and Freedoms of Researchers
- 4.1.3. Limits to the Right of Research
- 4.1.4. Ethical Principles of Clinical Research
- 4.1.5. Conclusions

4.2. Ethical Evaluation of Clinical Research on Drugs and Medical Devices
- 4.2.1. Introduction
- 4.2.2. Areas of Bioethics
  - 4.2.2.1. General Aspects
  - 4.2.2.2. Research Ethics
- 4.2.3. Justification of Bioethics
  - 4.2.3.1. Clinical Indeterminacy
  - 4.2.3.2. Relevance of Scientific Objectives
  - 4.2.3.3. Preclinical Data
- 4.2.4. Ethical Conditions of Clinical Trial Designs
- 4.2.5. Drug Research Ethics Committees
  - 4.2.5.1. Definition
  - 4.2.5.2. Functions
  - 4.2.5.3. Composition
  - 4.2.5.4. Conclusions

4.3. Subject Selection in Clinical Trials
- 4.3.1. Criteria
- 4.3.2. Special Patients and Vulnerability
- 4.3.3. Vulnerability Assessment
  - 4.3.3.1. Age
  - 4.3.3.2. Severity of Disease
  - 4.3.3.3. Other Types of Vulnerability
  - 4.3.3.4. Vulnerability Protection
- 4.3.4. Conclusions

4.4. Risk-Benefit Balance in Clinical Trials
- 4.4.1. Potential Benefits
- 4.4.2. Potential Risks
- 4.4.3. Minimizing Risks
- 4.4.4. Risk Level Assessment
- 4.4.5. Final Assessment of the Risk-Benefit Balance
- 4.4.6. Conclusions

4.5. Protection, Informed Consent and Participant Information Form
- 4.5.1. Participant Information Form (PIF)
  - 4.5.1.1. Type of Information Provided
  - 4.5.1.2. Information Processing
- 4.5.2. Informed Consent
  - 4.5.2.1. Concepts
  - 4.5.2.2. Obtaining Procedure
  - 4.5.2.3. Clinical Trials with Minors
  - 4.5.2.4. Clinical Trials with Patients with Modified Capacity to Give Consent
  - 4.5.2.5. Clinical Trials in Emergency Situations
  - 4.5.2.6. Clinical Trials in Pregnant or Breastfeeding Women
  - 4.5.2.7. Clinical trials on the Disabled
  - 4.5.2.8. Informed Consent for Genetic Studies
- 4.5.3. Insurance and Financial Compensation
  - 4.5.3.1. Safety
  - 4.5.3.2. Indemnification
  - 4.5.3.3. Compensation
- 4.5.4. Confidentiality
- 4.5.5. Violations
- 4.5.6. Continuation of Treatment After the Trial
- 4.5.7. Conclusions

4.6. Good Clinical Practices in Clinical Trials
- 4.6.1. History
- 4.6.2. Legal and Ethical Framework
- 4.6.3. Guideline for Good Clinical Practice (GCP)
  - 4.6.3.1. Basic Principles
  - 4.6.3.2. Drug Research Ethics Committee (CEIM)
  - 4.6.3.3. Researcher
  - 4.6.3.4. Promoter
  - 4.6.3.5. Protocol
  - 4.6.3.6. Investigators Brochure (IB)
  - 4.6.3.7. Promoters Manual
  - 4.6.3.8. Essential Documents
- 4.6.4. Conclusions

4.7. Legislation on Clinical Trials with Drugs and Medical Devices
- 4.7.1. Introduction
- 4.7.2. Drugs Used in Clinical Trials
  - 4.7.2.1. Manufacturing and Importation
  - 4.7.2.2. Labelling
  - 4.7.2.3. Acquisition
  - 4.7.2.4. Unused Drugs
- 4.7.3. European Legislation
- 4.7.4. FDA, EMA and AEMPS
- 4.7.5. Communication
- 4.7.6. Conclusions

4.8. Legislation on Clinical Trials with Healthcare Products
- 4.8.1. Introduction
- 4.8.2. Clinical Research with Medical Devices
- 4.8.3. European Legislation
- 4.8.4. Conclusions

4.9. Authorization and Registration Procedures for Drugs and Medical Devices
- 4.9.1. Introduction
- 4.9.2. Definitions
- 4.9.3. Drugs Authorization
- 4.9.4. Drugs Dispensing
- 4.9.5. Public Funding
- 4.9.6. Conclusions

4.10. Legislation on Post-Authorization Studies
- 4.10.1. What are Post-Authorization Trials?
- 4.10.2. Studies Justification
- 4.10.3. Classification
  - 4.10.3.1. Security/Safety
  - 4.10.3.2. Drug Utilization Studies (DUS)
  - 4.10.3.3. Pharmacoeconomic Studies
- 4.10.4. Guidelines
- 4.10.5. Administrative Procedures
- 4.10.6. Conclusions

Module 5. Monitoring of Clinical Trials I

5.1. Promoter I
- 5.1.1. General Aspects
- 5.1.2. Promoters Responsibilities

5.2. Promoter II
- 5.2.1. Project Management
- 5.2.2. Non-commercial Research

5.3. Protocol
- 5.3.1. Definition and Content
- 5.3.2. Protocol Compliance

5.4. Monitoring
- 5.4.1. Introduction
- 5.4.2. Definition
- 5.4.3. Monitoring Objectives
- 5.4.4. Types of Monitoring: Traditional and Risk-Based

5.5. Clinical Trial Monitor I
- 5.5.1. Who can be a Monitor?
- 5.5.2. CRO: Clinical Research Organization
- 5.5.3. Monitoring Plan

5.6. Clinical Monitor II
- 5.6.1. Monitor's Responsibilities
- 5.6.2. Verification of Source Documents Source Documents Verification (SDV)
- 5.6.3. Monitor's Report and Monitoring Letter

5.7. Selection Visit
- 5.7.1. Researcher Selection
- 5.7.2. Aspects to take into account
- 5.7.3. Suitability of Facilities
- 5.7.4. Visit to other Hospital Services
- 5.7.5. Deficiencies in Study Facilities and Staffing

5.8. *Start Up* in a Clinical Research Center
- 5.8.1. Definition and Functionality
- 5.8.2. Essential Documents at the Beginning of the Trial

5.9. Initiation Visit
- 5.9.1. Objective
- 5.9.2. Preparing the Initiation Visit
- 5.9.3. Investigators File
- 5.9.4. Investigator Meeting

5.10. Hospital Pharmacy Initiation Visit
- 5.10.1. Objective
- 5.10.2. Investigational Drug Management
- 5.10.3. Controlling Temperature
- 5.10.4. General Deviation Procedure

Module 6. Monitoring of Clinical Trials II

6.1. Follow-Up Visit
- 6.1.1. Preparation
  - 6.1.1.1. Letter Confirming the Visit
  - 6.1.1.2. Preparation
- 6.1.2. Center Development
  - 6.1.2.1. Documentation Review
  - 6.1.2.2. SAEs
  - 6.1.2.3. Inclusion and Exclusion Criteria
  - 6.1.2.4. Collate
- 6.1.3. Research Team Training
  - 6.1.3.1. Monitoring
    - 6.1.3.1.1. Monitoring Report Preparation
    - 6.1.3.1.2. Issues Tracking
    - 6.1.3.1.3. Team Support
    - 6.1.3.1.4. Monitoring Letter
  - 6.1.3.2. Temperature
    - 6.1.3.2.1. Adequate Medication
    - 6.1.3.2.2. Reception
    - 6.1.3.2.3. Expiration
    - 6.1.3.2.4. Dispensing
    - 6.1.3.2.5. Setting Up
    - 6.1.3.2.6. Return
    - 6.1.3.2.7. Storage
    - 6.1.3.2.8. Documentation
  - 6.1.3.3. Samples
    - 6.1.3.3.1. Local and Central
    - 6.1.3.3.2. Types
    - 6.1.3.3.3. Temperature Registration
    - 6.1.3.3.4. Calibration/Maintenance Certificate
  - 6.1.3.4. Meeting with the Research Team
    - 6.1.3.4.1. Signature of Pending Documentation
    - 6.1.3.4.2. Discussion of Findings
    - 6.1.3.4.3. Re-Training
    - 6.1.3.4.4. Corrective Actions
  - 6.1.3.5. Review of ISF (Investigator Site File)
    - 6.1.3.5.1. Clinical Investigations (CIs) and Protocols
    - 6.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS
    - 6.1.3.5.3. LOGs
    - 6.1.3.5.4. Site Visit Letter
    - 6.1.3.5.5. New Documentation
  - 6.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)
    - 6.1.3.6.1. Concept
    - 6.1.3.6.2. Principal Investigator Review
  - 6.1.3.7. Electronic Notebook

6.2. Close-Out Visit
- 6.2.1. Definition
- 6.2.2. Reasons for Close-Out Visits
  - 6.2.2.1. Completion of the Clinical Trial
  - 6.2.2.2. Not Complying with Protocol
  - 6.2.2.3. Not Complying with Good Clinical Practices
  - 6.2.2.4. At the Investigators Request
  - 6.2.2.5. Low Recruitment
- 6.2.3. Procedures and Responsibilities
  - 6.2.3.1. Before the Close-Out Visit
  - 6.2.3.2. During the Close-Out Visit
  - 6.2.3.3. After the Close-Out Visit
- 6.2.4. Pharmacy Close-Out Visit
- 6.2.5. Final Report
- 6.2.6. Conclusions

6.3. "Queries Management", Database Slicing
- 6.3.1. Definition
- 6.3.2. Queries Rules
- 6.3.3. How are Queries Generated?
  - 6.3.3.1. Automatically
  - 6.3.3.2. By the Monitor
  - 6.3.3.3. By an External Reviewer
- 6.3.4. When are "Queries" Generated?
  - 6.3.4.1. After a Monitoring Visit
  - 6.3.4.2. Close to Closing a Database
- 6.3.5. Query Status
  - 6.3.5.1. Open
  - 6.3.5.2. Pending Revision
  - 6.3.5.3. Closed
- 6.3.6. Database Slicing
  - 6.3.6.1. Most Frequent Database Slicing Errors
- 6.3.7. Conclusions

6.4. AE Management and SAE Notification
- 6.4.1. Definitions
  - 6.4.1.1. Adverse Events "Adverse Event" (AE)
  - 6.4.1.2. Adverse Reactions (AR)
  - 6.4.1.3. "Serious Adverse Event"(SAE) or Serious Adverse Reaction (SAR)
  - 6.4.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR) SUSAR
- 6.4.2. Data to be Collected by the Researcher
- 6.4.3. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
  - 6.4.3.1. Description
  - 6.4.3.2. Dates
  - 6.4.3.3. Unraveling
  - 6.4.3.4. Intensity
  - 6.4.3.5. Actions Taken
  - 6.4.3.6. Causality Relationship
  - 6.4.3.7. Basic Questions
    - 6.4.3.7.1. Who reports? What is reported? To whom is it reported? How is it reported? When is it reported?
- 6.4.4. Procedures for the Communication of AE/AR with Investigational Drugs
  - 6.4.4.1. Expedited Notification of Individual Cases
  - 6.4.4.2. Periodic Security Reports
  - 6.4.4.3. Ad Hoc Safety Reports
  - 6.4.4.4. Annual Reports
- 6.4.5. Special Interest Events
- 6.4.6. Conclusions

6.5. Clinical Research Associate (CRA) Standard Operating Procedures Standard Operating Procedures (SOP)
- 6.5.1. Definition and objectives
- 6.5.2. Writing a SOP
  - 6.5.2.1. Procedure
  - 6.5.2.2. Format
  - 6.5.2.3. Implementation
  - 6.5.2.4. Review
- 6.5.3. SOP Feasibility and Site Qualification Visit
  - 6.5.3.1. Procedures
- 6.5.4. Standard Operating Procedures (SOP) for the Initial Visit
  - 6.5.4.1. Procedures Prior to the Initiation Visit
  - 6.5.4.2. Procedures During the Initiation Visit
  - 6.5.4.3. Monitoring Initiation Visit Procedures
- 6.5.5. SOP for Monitoring Visit
  - 6.5.5.1. Procedures Prior to the Monitoring Visit
  - 6.5.5.2. Procedures During the Monitoring Visit
  - 6.5.5.3. Monitoring Letter
- 6.5.6. SOP for Close-Out Visit
  - 6.5.6.1. Preparing the Close-Out Visit
  - 6.5.6.2. Manage the Close-Out Visit
  - 6.5.6.3. Monitoring After a Close-Up Visit
- 6.5.7. Conclusions

6.6. Quality Guarantee. Audits and Inspections
- 6.6.1. Definition
- 6.6.2. Types of Audits
  - 6.6.2.1. Internal Audits
  - 6.6.2.2. External Audits or Inspections
- 6.6.3. How to Prepare an Audit?
- 6.6.4. Principal Findings
- 6.6.5. Conclusions

6.7. Protocol Deviations
- 6.7.1. Criteria
  - 6.7.1.1. Non-Compliance with Inclusion Criteria
  - 6.7.1.2. Compliance with Exclusion Criteria
- 6.7.2. International Classification of Functioning (ICF) Deficiencies
  - 6.7.2.1. Correct Signatures on Documents (CI, LOG)
  - 6.7.2.2. Correct Dates
  - 6.7.2.3. Correct Documentation
  - 6.7.2.4. Correct Storage
  - 6.7.2.5. Correct Version
- 6.7.3. Out-Of-Window Visits
- 6.7.4. Poor or Wrong Documentation
- 6.7.5. The 5 Rights Medication Administration
  - 6.7.5.1. Right Patient
  - 6.7.5.2. Right Drug
  - 6.7.5.3. Right Time
  - 6.7.5.4. Right Dose
  - 6.7.5.5. Right Route
- 6.7.6. Missing Samples and Parameters
  - 6.7.6.1. Missing Samples
  - 6.7.6.2. Parameter Not Performed
  - 6.7.6.3. Sample Not Sent On Time
  - 6.7.6.4. Time of Sample Collection
  - 6.7.6.5. Request for Kits Out of Time
- 6.7.7. Information Privacy
  - 6.7.7.1. Information Security
  - 6.7.7.2. Reporting Security
  - 6.7.7.3. Photo Security
- 6.7.8. Temperature Deviations
  - 6.7.8.1. Register
  - 6.7.8.2. Inform.
  - 6.7.8.3. Act
- 6.7.9. Open Blinding at the Wrong Time
- 6.7.10. PI Availability
  - 6.7.10.1. Not Updated in Interactive Voice Response Services (IVRS)
  - 6.7.10.2. Not Sent on Time
  - 6.7.10.3. Not Registered on Time
  - 6.7.10.4. Broken Stock
- 6.7.11. Forbidden Medication
- 6.7.12. Key and Non-Key

6.8. Source and Essential Documents
- 6.8.1. Features
- 6.8.2. Source Documents Location
- 6.8.3. Source Document Access
- 6.8.4. Source Document Types
- 6.8.5. How to Correct a Source Document?
- 6.8.6. Source Document Retention Time
- 6.8.7. Main Components of the Medical History
- 6.8.8. Investigator's Brochure (IB)

6.9. Monitoring Plan
- 6.9.1. Visits
- 6.9.2. Frequency (F)
- 6.9.3. Organization
- 6.9.4. Confirmation
- 6.9.5. Site Issues Categorization
- 6.9.6. Communication with Researchers
- 6.9.7. Research Team Training
- 6.9.8. Trial Master File
- 6.9.9. Reference Documents
- 6.9.10. Electronic Notebooks Remote Review
- 6.9.11. Data Privacy
- 6.9.12. Center Management Activities

6.10. Data Collection Notebooks
- 6.10.1. Concept and History
- 6.10.2. Timeline Compliance
- 6.10.3. Data Validation
- 6.10.4. Management of Data Inconsistencies or Queries
- 6.10.5. Data Exports
- 6.10.6. Security and Roles
- 6.10.7. Traceability and Logs
- 6.10.8. Report Generation
- 6.10.9. Notifications and Alerts
- 6.10.10. Electronic Notebook Vs. Paper Notebook

Module 7. Coordination of Clinical Trials I

7.1. The Researcher's File - General Aspects
- 7.1.1. What is the Researcher's File? What type of Documentation Should It Contain and Why? How Long Should the Information be Stored?
- 7.1.2. Contract
  - 7.1.2.1. Original Copies
  - 7.1.2.2. Amendments
- 7.1.3. Ethical Committees
  - 7.1.3.1. Approvals
  - 7.1.3.2. Amendments
- 7.1.4. Regulatory Authorities
  - 7.1.4.1. Approvals
  - 7.1.4.2. Modifications
  - 7.1.4.3. Monitoring and Final Reports
- 7.1.5. Civil Liability Insurance

7.2. Documentation Associated with the Research Team
- 7.2.1. CV
- 7.2.2. Good Clinical Practice Certificate
- 7.2.3. Specific Education Certificates
- 7.2.4. Signed Statement of the Investigator, Financial Disclosure
- 7.2.5. Task Delegation

7.3. Study Protocol and Monitoring
- 7.3.1. Protocol Versions, Summary and Pocket Guides
- 7.3.2. Protocol
- 7.3.3. Protocol Amendments
- 7.3.4. Protocol Signature Form

7.4. Patient Related Material
- 7.4.1. Patient Information Form and Informed Consent Form (Copies and Specimens for Signature)
- 7.4.2. Modifications to the Consent (Copies and Specimens for Signature)
- 7.4.3. Study Participation Cards
- 7.4.4. Information for Primary Care Physicians
- 7.4.5. Questionnaires

7.5. Patient Forms, Monitoring Visits
- 7.5.1. Patient Screening Form
- 7.5.2. Patient Recruitment and Identification Form
- 7.5.3. Visit Logs and Reports Form

7.6. Data Collection Notebooks (DCNs)
- 7.6.1. Types
- 7.6.2. Guide or Manual for Data Entry in the DCN
- 7.6.3. Copy of DCN

7.7. Investigator's Brochure (Studies with Medical Devices) or Fact Sheet (Clinical Trials with Medication)
- 7.7.1. Investigators Brochure (IB)
- 7.7.2. Technical Data Sheets of the Drugs Under Study (If Marketed)
- 7.7.3. Instructions for the Control of Specific Parameters (e.g. Temperature)
- 7.7.4. Instructions for Return of Medication or Medical Devices

7.8. Material Related to Laboratory and Specific Procedures
- 7.8.1. Central Laboratories and Sample Shipping Documents
- 7.8.2. Local Laboratory: Qualification Certificates and Ranks
- 7.8.3. Instructions for Acquiring and/or Processing Medical Images
- 7.8.4. Sample and Material Shipment

7.9. Security/Safety
- 7.9.1. Adverse Events and Serious Adverse Events
- 7.9.2. Notification Instructions
- 7.9.3. Relevant Security Correspondence

7.10. Others
- 7.10.1. Contact Information
- 7.10.2. "Note to File"
- 7.10.3. Correspondence with the Promoter
- 7.10.4. Acknowledgements of Receipt
- 7.10.5. Newsletter

Module 8. Coordination of Clinical Trials II

8.1. Research Team
- 8.1.1. Components of a Research Team
  - 8.1.1.1. Principal Investigator
  - 8.1.1.2. Sub-Investigator
  - 8.1.1.3. Coordinator
  - 8.1.1.4. Rest of the Team
- 8.1.2. Responsibilities of the Research Team
  - 8.1.2.1. Compliance with Good Clinical Practices and Current Legislation
  - 8.1.2.2. Compliance of the Study Protocol
  - 8.1.2.3. Care and Maintenance of the Research Archive
- 8.1.3. Task Delegation
  - 8.1.3.1. Document Details
  - 8.1.3.2. Example

8.2. Trial Coordinator
- 8.2.1. Responsibilities
  - 8.2.1.1. Primary Responsibilities
  - 8.2.1.2. Secondary Responsibilities
- 8.2.2. Capabilities and Competencies
  - 8.2.2.1. Academic Background
  - 8.2.2.2. Skills
- 8.2.3. Clinical Trials vs. Observational Study
  - 8.2.3.1. Types of Clinical Trials
  - 8.2.3.2. Types of Observational Studies

8.3. Protocol
- 8.3.1. Primary and Secondary Objectives
  - 8.3.1.1. What Are They and Who Defines Them?
  - 8.3.1.2. Importance During the Course of the Clinical Trial
- 8.3.2. Inclusion and Exclusion Criteria
  - 8.3.2.1. Inclusion Criteria
  - 8.3.2.2. Exclusion Criteria
  - 8.3.2.3. Example

8.3.3. Flowchart
8.3.3.1. Document and Explanation
8.3.4. Concomitant Medication and Prohibited Medication
8.3.4.1. Concomitant Drug
8.3.4.2. Forbidden Medication
8.3.4.3. Washout Periods
8.4. Documentation Required to Initiate Clinical Trial
8.4.1. Curriculum of the Research Team
8.4.1.1. Basic Notions of a Research Curriculum
8.4.1.2. Good Clinical Practice Example
8.4.2. Good Clinical Practice
8.4.2.1. Origin of Good Clinical Practices
8.4.2.2. How to Get Certified?
8.4.2.3. Expiration
8.4.3. Suitability of the Research Team
8.4.3.1. Who Signs the Document?
8.4.3.2. Presentation to Ethics Committee
8.4.4. Suitability of Facilities
8.4.4.1. Who Signs the Document?
8.4.4.2. Ethical Committee Presentation
8.4.5. Calibration Certificates
8.4.5.1. Calibration
8.4.5.2. Calibration Equipment
8.4.5.3. Valid Certifications
8.4.5.4. Expiration
8.4.6. Other Training
8.4.6.1. Necessary Certifications According Protocol
8.5. Main Functions Trial Coordinator
8.5.1. Documentation Preparation
8.5.1.1. Documentation Requested for Approval of the Study at the Center
8.5.2. Investigator Meeting
8.5.2.1. Importance
8.5.2.2. Attendees
8.5.3. Initiation Visit
8.5.3.1. Duties of the Coordinator
8.5.3.2. Functions of the Principal Investigator and Subinvestigators
8.5.3.3. Promoter
8.5.3.4. Monitor
8.5.4. Monitoring Visit
8.5.4.1. Preparation After a Monitoring Visit
8.5.4.2. Functions During the Monitoring Visit
8.5.5. End-Of-Study Visit
8.5.5.1. Storage of the Researchers File
8.6. Relationship with the Patient
8.6.1. Preparation of Visits
8.6.1.1. Consents and Amendments
8.6.1.2. Visit Window
8.6.1.3. Identify the Responsibilities of the Investigation Team during the Visit
8.6.1.4. Visit Calculator
8.6.1.5. Preparation of Documentation to be Used During the Visit
8.6.2. Complementary Tests
8.6.2.1. Analysis
8.6.2.2. Chest X-Ray
8.6.2.3. Electrocardiogram
8.6.3. Calendar of Visits
8.6.3.1. Example
8.7. Samples
8.7.1. Equipment and Materials Necessary
8.7.1.1. Centrifuge
8.7.1.2. Incubator
8.7.1.3. Refrigerators
8.7.2. Processing of Samples
8.7.2.1. General Procedure
8.7.2.2. Example
8.7.3. Laboratory Kits
8.7.3.1. What are they?
8.7.3.2. Expiration

8.7.4. Shipment of Samples
8.7.4.1. Sample Storage
8.7.4.2. Ambient Temperature Shipment
8.7.4.3. Shipping Frozen Samples
8.8. Data Collection Notebooks
8.8.1. What Is It?
8.8.1.1. Types of Notebooks
8.8.1.2. Paper Notebook
8.8.1.3. Electronic Notebook
8.8.1.4. Specific Notebooks According to Protocol
8.8.2. How To Complete It?
8.8.2.1. Example
8.8.3. Query
8.8.3.1. What Is a Query?
8.8.3.2. Resolution Time
8.8.3.3. Who Can Open a Query?
8.9. Randomization Systems
8.9.1. What Is It?
8.9.2. Types of IWRS:
8.9.2.1. Telephonic
8.9.2.2. Electronic
8.9.3. Responsibilities Researcher Vs. Research Team
8.9.3.1. Screening
8.9.3.2. Randomization
8.9.3.3. Scheduled Visits
8.9.3.4. Unscheduled Visits
8.9.3.5. Blinding Opening
8.9.4. Medication
8.9.4.1. Who Receives the Medication?
8.9.4.2. Drug Traceability
8.9.5. Return of Medication
8.9.5.1. Functions of the Research Team in the Return of Medication
8.10. Biological Treatments
8.10.1. Coordination of Clinical Trials with Biologicals
8.10.1.1. Biological Treatments
8.10.1.2. Types of Treatment
8.10.2. Types of Studies
8.10.2.1. Biological Criteria Placebo
8.10.2.2. Biological Criteria Biological Criteria
8.10.3. Biological Management
8.10.3.1. Administration.
8.10.3.2. Traceability
8.10.4. Rheumatic Diseases
8.10.4.1. Rheumatoid Arthritis.
8.10.4.2. Psoriatic Arthritis
8.10.4.3. Lupus
8.10.4.4. Scleroderma

Module 9. Follow-up of Patients in Clinical Trials

9.1. Patient Care in Outpatient Clinics
9.1.1. Visits in the Protocol
9.1.1.1. Visits and Procedures
9.1.1.2. Window of Realization of the Different Visits
9.1.1.3. Database Considerations
9.2. Materials Used in the Different Study Visits
9.2.1. Questionnaires
9.2.2. Drug Adherence Cards
9.2.3. Symptom Cards
9.2.4. Study Card
9.2.5. Electronic Devices
9.2.6. Suicide Risk Scales
9.2.7. Material for the Displacement of Patients
9.2.8. Others
9.3. Strategies for Patient Retention
9.3.1. Possible Causes for Abandonment of a Clinical Trial
9.3.2. Strategies and Solutions to the Possible Causes of Abandonment
9.3.3. Long-Term Monitoring of Patients Leaving the Study Prematurely
9.4. Loss of Patient Follow-Up
9.4.1. Definition of Loss of Monitoring
9.4.2. Causes of Loss of Monitoring
9.4.3. Resumption of Monitoring
9.4.3.1. Re-Inclusion Back into the Protocol

9.5. Adherence to Pharmacological Treatment under Study
- 9.5.1. Calculation of Adherence to Pharmacological Treatment
- 9.5.2. Risk Factors for Therapeutic Non-Compliance
- 9.5.3. Strategies to Strengthen Adherence to Treatment
- 9.5.4. Treatment Dropout
- 9.5.5. Study Drug Interactions

9.6. Monitoring of Adverse Reactions and Symptom Management in the Study Medication Administration
- 9.6.1. Study Medication
  - 9.6.1.1. Different Drug Presentations
  - 9.6.1.2. Procedure and Preparation of Study Medication
- 9.6.2. Drug-Related Adverse Reactions
- 9.6.3. Non-Drug Related Adverse Reactions
- 9.6.4. Adverse Reaction Treatment

9.7. Monitoring of Patient Attendance at Study Visits
- 9.7.1. Visit Calculator
- 9.7.2. Study Visits Control
- 9.7.3. Tools for Compliance and Visitor Control

9.8. Difficulties in Patient Monitoring Within a Clinical Trial
- 9.8.1. Problems Related to Adverse Patient Events
- 9.8.2. Problems Related to the Patients Work Situation
- 9.8.3. Problems Related to the Patients Residence
- 9.8.4. Problems Related to the Patients Legal Status
- 9.8.5. Solutions and their Treatments

9.9. Monitoring of Patients in Treatment with Psychopharmaceuticals

9.10. Monitoring of Patients During Hospitalization

Module 10. Biostatistics

10.1. Study Design
- 10.1.1. Research Question
- 10.1.2. Population to Analyze

10.1.3. Classification
10.1.3.1. Comparison between Groups
10.1.3.2. Maintenance of the Described Conditions
10.1.3.3. Assignment to Treatment Group
10.1.3.4. Degree of Masking
10.1.3.5. Modality of Intervention
10.1.3.6. Centers Involved
10.2. Types of Randomized Clinical Trials: Validity and Biases
10.2.1. Types of Clinical Trials
10.2.1.1. Superiority Study
10.2.1.2. Equivalence or Bioequivalence Study
10.2.1.3. Non-Inferiority Study
10.2.2. Analysis and Validity of Results
10.2.2.1. Internal Validity
10.2.2.2. External Validity
10.2.3. Biases
10.2.3.1. Selection
10.2.3.2. Measurement
10.2.3.3. Confusion
10.3. Sample Size Protocol Deviations
10.3.1. Parameters Used
10.3.2. Protocol Justification
10.3.3. Protocol Deviations
10.4. Methodology
10.4.1. Missing Data Handling
10.4.2. Statistical Methods
10.4.2.1. Description of Data
10.4.2.2. Survival
10.4.2.3. Logistic Regression
10.4.2.4. Mixed Models
10.4.2.5. Sensitivity Analysis
10.4.2.6. Multiplicity Analysis
10.5. When Does the Statistician Become Part of the Project
10.5.1. Statistical Role
10.5.2. Points of the Protocol to be Reviewed and Described by the Statistician
10.5.2.1. Study Design
10.5.2.2. The Primary and Secondary Objectives of the Study
10.5.2.3. Sample Size Calculation
10.5.2.4. Variables
10.5.2.5. Statistical Justification
10.5.2.6. Material and Methods used to Study the Objectives of the Study
10.6. CRD Design
10.6.1. Information Gathering Variables Dictionary
10.6.2. Variables and Data Entry
10.6.3. Database Security, Testing and Debugging
10.7. Statistical Analysis Plan
10.7.1. Statistical Analysis Plan
10.7.2. When to Perform a Statistical Analysis Plan
10.7.3. Statistical Analysis Plan Parts
10.8. Intermediate Analysis
10.8.1. Reasons for an Early Stopping of a Clinical Trial
10.8.2. Implications of Early Termination of a Clinical Trial
10.8.3. Statistical Designs
10.9. Final Analysis
10.9.1. Final Report Criteria
10.9.2. Plan Deviations
10.9.3. Guidelines for the Elaboration of the Final Report of a Clinical Trial
10.10. Statistical Review of a Protocol
10.10.1. Checklist
10.10.2. Frequent Errors in the Review of a Protocol

07

Clinical Internship

After passing the online lesson evaluations, the program includes a period of Internship Program in a reference clinical center. In this way, the specialist will have access to the real work of professionals with extensive experience in the field. In addition, you will have at your disposal the support of a tutor who will accompany you throughout the process, both in the preparation and in the development of the clinical practices.

During 3 weeks you will get to know the real work of clinical trials, thanks to the practical training in a reference center"

The internship period of this Hybrid Professional Master's Degree in MBA Management and Monitoring of Clinical Trials consists of a 3-week intensive internship, from Monday to Friday with 8 consecutive hours of practical training with an associate specialist. This stay will allow the professional to participate and see firsthand how health research is carried out, through real work with specialized teams.

In this completely practical training proposal, the activities are aimed at developing and perfecting the competencies necessary for the management and monitoring of clinical trials. For this reason, during this period you will be able to contribute to the development of the different phases of a clinical trial, provide support in monitoring or facilitate the implementation of protocols for clinical trials through examples.

TECH provides an excellent opportunity to learn by working in an innovative center, where the monitoring of clinical trials is the key to the future of health research. In this way, one of the main objectives is to ensure that the professional obtains a complete update from the hands of true specialists in this field.

The practical part will be carried out with the active participation of the student performing the activities and procedures of each area of competence (learning to learn and learning to do), with the accompaniment and guidance of the professors and other fellow trainees that facilitate teamwork and multidisciplinary integration as transversal competencies for the clinical research praxis (learning to be and learning to relate).

The procedures described below will form the basis of the practical part of the training, and their completion is subject to both the suitability of the patients and the availability of the center and its workload, with the proposed activities being as follows:

Module	Practical Activity
Drug research and development techniques	Planning the development of a new drug
	Carrying out the necessary steps to obtain authorization for the use of a medicinal product
	Discovering and analyzing active substances, taking into account the exclusion criteria of the different regulatory entities
	Analyze and observe, applying the specific pharmacokinetic equations for each case, the absorption, distribution, metabolization, excretion and possible toxicity of a substance administered to a patient
Clinical trial development and monitoring methods and protocols.	Set up a clinical trial, taking into account the specific characteristics of a Phase 1 research study
	Conduct single and multiple dose trials, as well as pharmacodynamic and pharmacokinetic studies to test the efficacy and usefulness of the substance
	Carry out adequate data collection and administrative management in accordance with the needs of the trial
	Manage the samples accurately, taking into account their characteristics, in order to for proper preservation and transport
	Perform constant monitoring in the clinical trial, paying attention to elements such as storage of substances and samples and discussion of findings
	Coordinate the work team throughout the project, ensuring smooth communication between team members and external teams involved in the trial
Patient follow-up techniques in clinical trials	Draw up a visit plan for the patient participating in the Clinical Trial
	Establish a protocol for patient follow-up by means of questionnaires, and taking into account the use of drug adherence cards and other documents such as symptom cards or suicide risk scales
	Dictating a strategy to avoid the patient's abandonment of the clinical trial, starting from the causes behind this decision
	Follow the patient's condition, paying attention to the possible adverse effects of the drug

Civil Liability Insurance

This institution's main concern is to guarantee the safety of the trainees and other collaborating agents involved in the internship process at the company. Among the measures dedicated to achieve this is the response to any incident that may occur during the entire teaching-learning process.

To this end, this entity commits to purchasing a civil liability insurance policy to cover any eventuality that may arise during the course of the internship at the center.

This liability policy for interns will have broad coverage and will be taken out prior to the start of the practical training period. That way professionals will not have to worry in case of having to face an unexpected situation and will be covered until the end of the internship program at the center.

General Conditions of the Internship Program

The general terms and conditions of the internship agreement for the program are as follows:

1. TUTOR: During the Hybrid Professional Master's Degree, students will be assigned with two tutors who will accompany them throughout the process, answering any doubts and questions that may arise. On the one hand, there will be a professional tutor belonging to the internship center who will have the purpose of guiding and supporting the student at all times. On the other hand, they will also be assigned with an academic tutor whose mission will be to coordinate and help the students during the whole process, solving doubts and facilitating everything they may need. In this way, the student will be accompanied and will be able to discuss any doubts that may arise, both clinical and academic.

2. DURATION: The internship program will have a duration of three continuous weeks, in 8-hour days, 5 days a week. The days of attendance and the schedule will be the responsibility of the center and the professional will be informed well in advance so that they can make the appropriate arrangements.

3. ABSENCE: If the students does not show up on the start date of the Hybrid Professional Master's Degree, they will lose the right to it, without the possibility of reimbursement or change of dates. Absence for more than two days from the internship, without justification or a medical reason, will result in the professional's withdrawal from the internship, therefore, automatic termination of the internship. Any problems that may arise during the course of the internship must be urgently reported to the academic tutor.

4. CERTIFICATION: Professionals who pass the Hybrid Professional Master's Degree will receive a certificate accrediting their stay at the center.

5. EMPLOYMENT RELATIONSHIP: the Hybrid Professional Master's Degree shall not constitute an employment relationship of any kind.

6. PRIOR EDUCATION: Some centers may require a certificate of prior education for the Hybrid Professional Master's Degree. In these cases, it will be necessary to submit it to the TECH internship department so that the assignment of the chosen center can be confirmed.

7. DOES NOT INCLUDE: The Hybrid Professional Master's Degree will not include any element not described in the present conditions. Therefore, it does not include accommodation, transportation to the city where the internship takes place, visas or any other items not listed

However, students may consult with their academic tutor for any questions or recommendations in this regard. The academic tutor will provide the student with all the necessary information to facilitate the procedures in any case.

08

Where Can I Do the Clinical Internship?

In the healthcare field, research is essential for the discovery of new drugs and treatments. Undoubtedly, the best way to keep abreast of the latest developments in this sector is through practice and, therefore, this Hybrid Professional Master's Degree of TECH includes an intensive stay in a health center, a reference at the research level. In this way, after passing the theoretical content evaluations, the professional will be able to participate, for 3 weeks, in the work teams of a clinical institution, broadening their skills under the guidance of leading specialists in the field.

Access to a reference center where you can learn the ins and outs of Clinical Trials and expand your capabilities in a highly competitive field of research"

The student will be able to take the practical part of this Hybrid Professional Master's Degree in the following centers:

IdiPAZ

Country
Spain

City
Madrid

Management:
Paseo de la Castellana 261, Edificio Norte, 28046 Madrid

La Paz University Hospital Research Institute

Related internship programs:
Medical Research
- MBA in Management and Monitoring of Clinical Trials

Enroll now and advance in your field of work with a comprehensive program that will allow you to put into practice everything you have learned"

09

Methodology

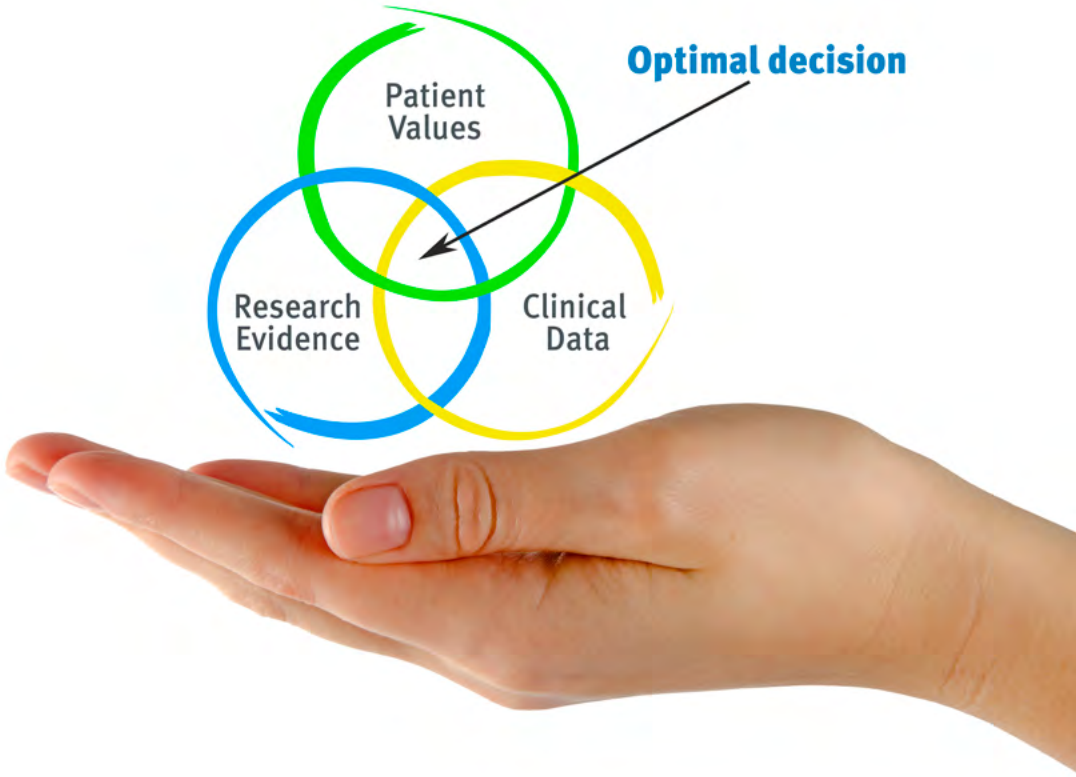
This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning.**
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine**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

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

At TECH we use the Case Method

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

With TECH you will experience a way of learning that is shaking the foundations of traditional universities around the world.



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

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

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

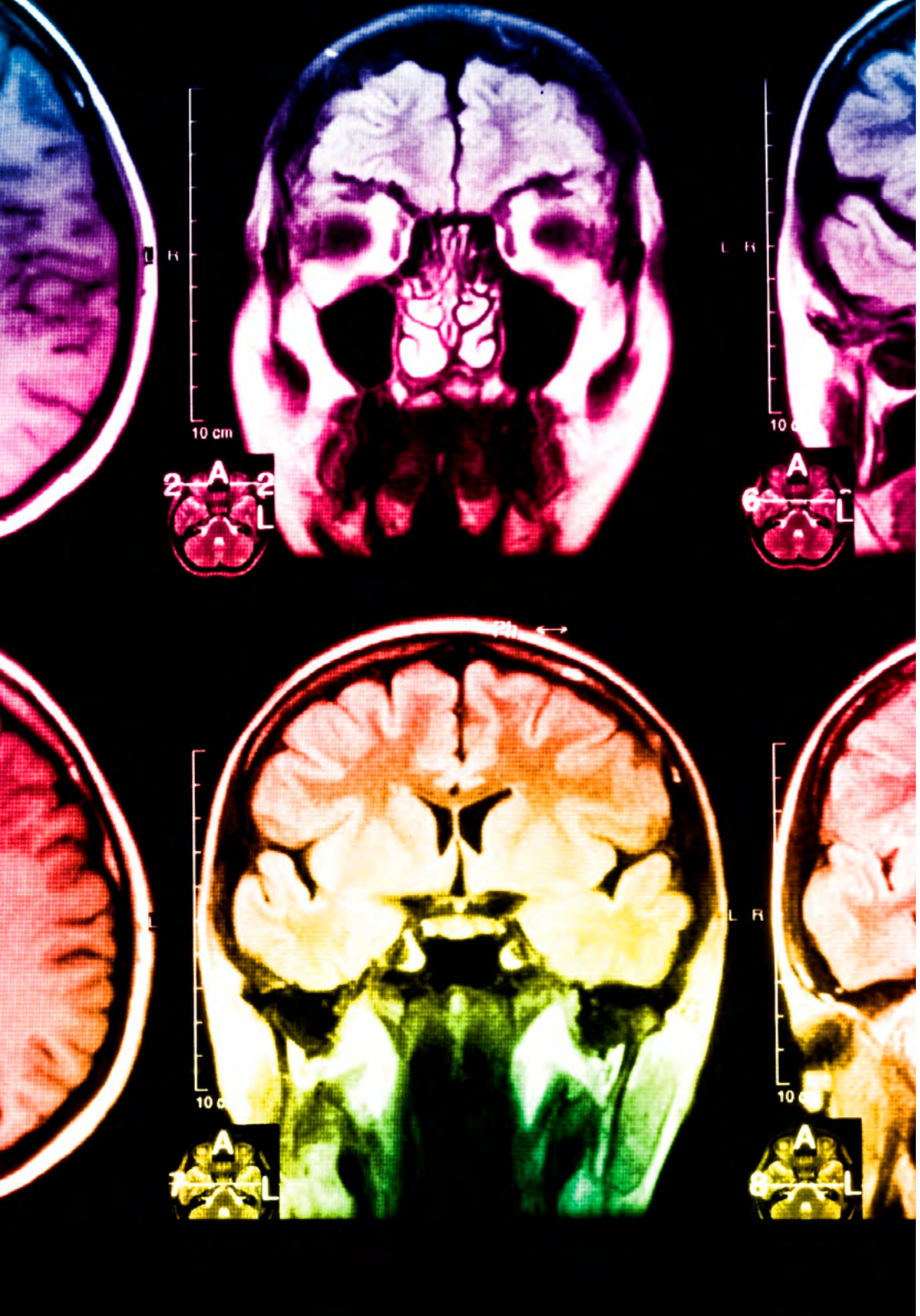
1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better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

Relearning Methodology

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

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

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



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

With this methodology, more than 250,000 physicians have been trained with unprecedented success in all clinical specialties regardless of surgical load. Our pedagogical methodology is developed in a highly competitive environment, with a university student body with a strong socioeconomic profile and an average age of 43.5 years old.

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

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

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

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

Study Material

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

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

Surgical Techniques and Procedures on Video

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

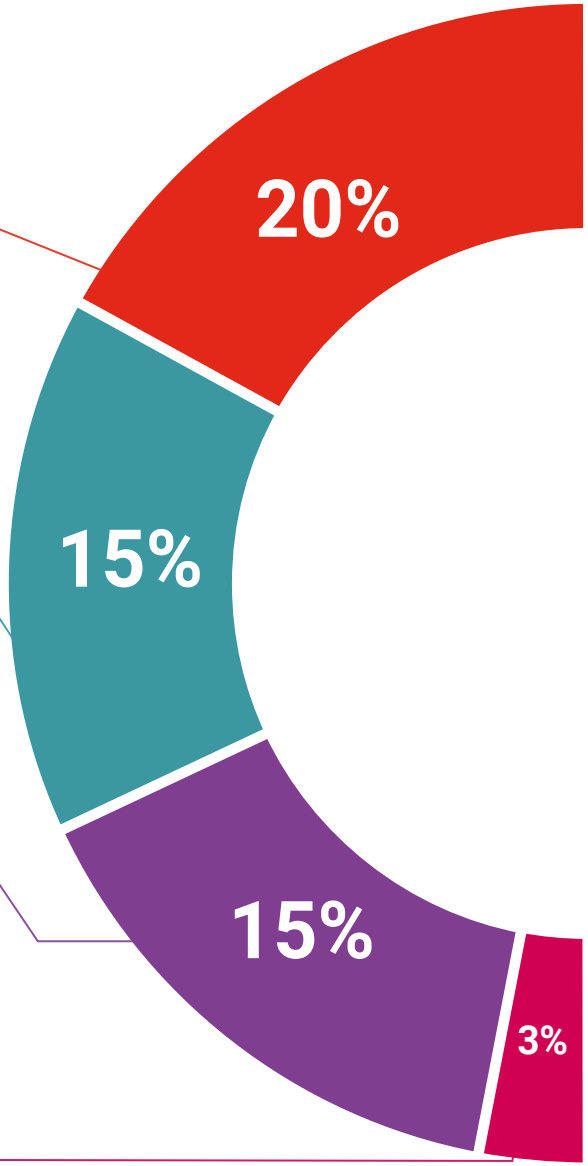
Interactive Summaries

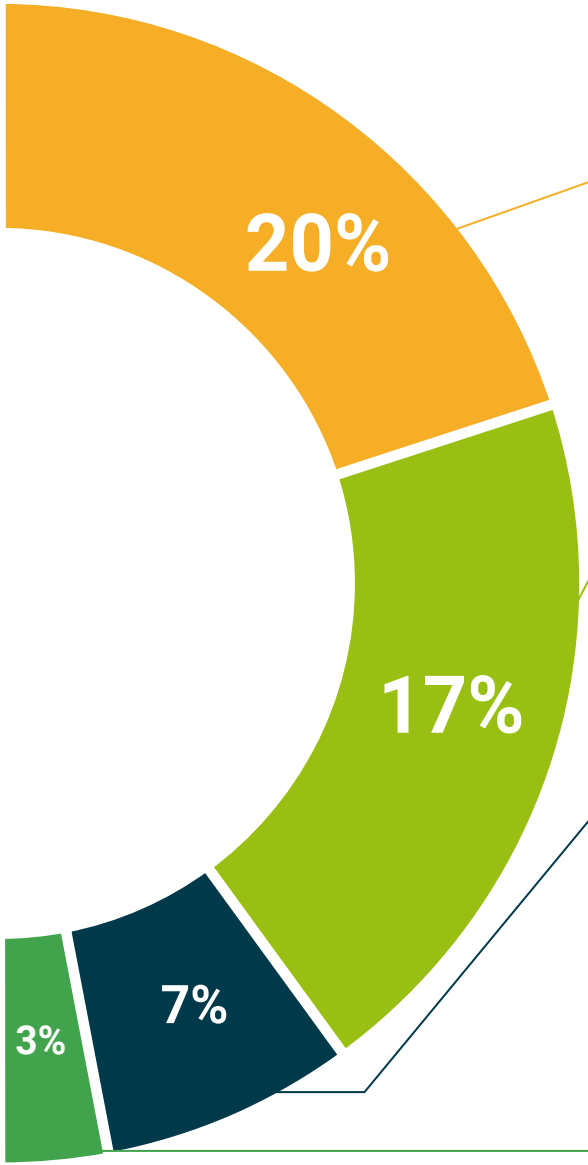
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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

Additional Reading

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





Expert-Led Case Studies and Case Analysis

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

Testing & Retesting

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

Classes

There is scientific evidence on the usefulness of learning by observing experts. The system known as Learning from an Expert strengthens knowledge and memory, and generates confidence in future difficult decisions.

Quick Action Guides

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

10

Certificate

The Professional Master's Degree in MBA Management and Monitoring of Clinical Trials guarantees students, in addition to the most rigorous and updated training, access to a Hybrid Professional Master's Degree issued by TECH Technological University

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

This **Hybrid Professional Master's Degree in MBA Management and Monitoring of Clinical Trials** contains the most complete and up-to-date program on the professional and educational field.

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

In addition to the Certificate, students will be able to obtain an academic transcript, as well as a certificate outlining the contents of the program. In order to do so, students should contact their academic advisor, who will provide them with all the necessary information.

Certificate: **Hybrid Professional Master's Degree in MBA Management and Monitoring of Clinical Trials**

Course Modality: **Hybrid (Online + Clinical Internship)**

Duration: **12 months.**

Certificate: **TECH Technological University**

Teaching Hours: **1,620 hours.**

tech technological university

Awards the following

CERTIFICATE

to

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

For having successfully passed and accredited the following program

HYBRID PROFESSIONAL MASTER'S DEGREE

in

MBA Management and Monitoring of Clinical Trials

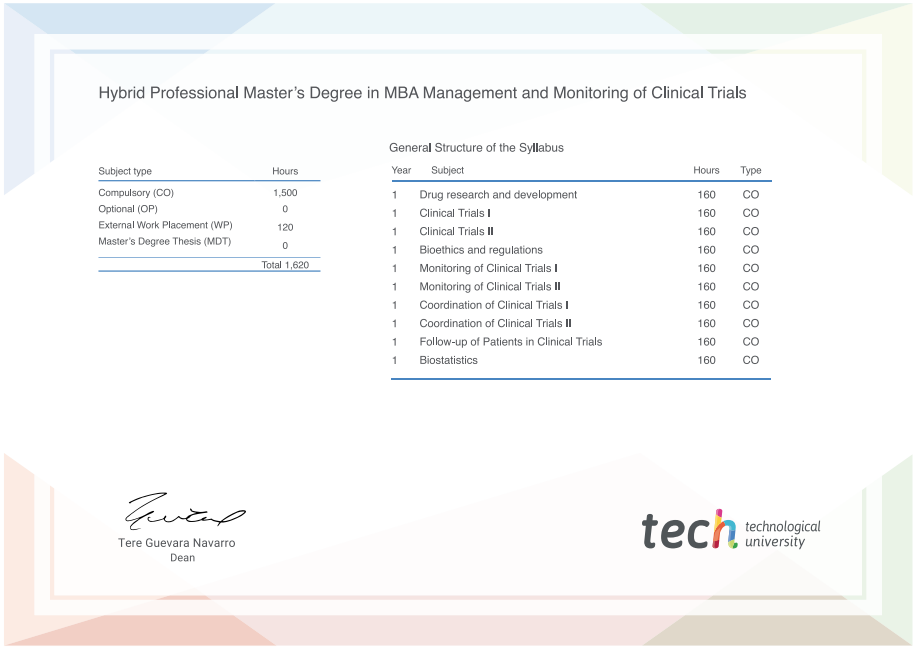
This is a qualification awarded by this University, with a duration of 1,620 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

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

June 17, 2020

Tere Guevara Navarro
Dean

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



Hybrid Professional Master's Degree in MBA Management and Monitoring of Clinical Trials

Subject type	Hours
Compulsory (CO)	1,500
Optional (OP)	0
External Work Placement (WP)	120
Master's Degree Thesis (MDT)	0
	Total 1,620

General Structure of the Syllabus

Year	Subject	Hours	Type
1	Drug research and development	160	CO
1	Clinical Trials I	160	CO
1	Clinical Trials II	160	CO
1	Bioethics and regulations	160	CO
1	Monitoring of Clinical Trials I	160	CO
1	Monitoring of Clinical Trials II	160	CO
1	Coordination of Clinical Trials I	160	CO
1	Coordination of Clinical Trials II	160	CO
1	Follow-up of Patients in Clinical Trials	160	CO
1	Biostatistics	160	CO

Tere Guevara Navarro
Dean

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

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Hybrid Professional Master's Degree

MBA Management and Monitoring of Clinical Trials

Course Modality: **Hybrid (Online + Clinical Internship)**
Duration: **12 months.**
Certificate: **TECH Technological University**
Teaching Hours: **1,620 hours.**

Hybrid Professional Master's Degree

MBA Management and Monitoring of Clinical Trials

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