Hybrid Master's Degree

MBA in Clinical Trials Management and Monitoring

tech global university

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Hybrid Master's Degree

MBA in Clinical Trials Management and Monitoring

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

Duration: **12 months**

Certificate: **TECH Global University**

60 + 4 ECTS Credits

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

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Introduction

Health crises, especially the one experienced after the last pandemic caused by COVID-19, have led to an increase in research funding. Likewise, the race to find more effective drugs and new pharmacological solutions to diseases, especially those resistant to antibiotics, continues. In this scenario, it is vital that pharmacists update their knowledge. This is why TECH offers this program, where the graduate will learn about the most recent developments in clinical trials and team management in this field. All this in a 100% online theoretical framework, complemented by a practical stay in a reference clinical research center. An environment where you will be able to work alongside other professionals with extensive experience in this field, who will show you the latest advances and techniques in clinical trials.

In just 12 months you will be able to access the most relevant theoretical and practical information on drug development and research team coordination"

In recent years, the public and public administrations have become more aware of the importance of health research. As a result, there has been an increase in investment in this area, benefiting not only patients, who finally obtain effective drugs, but also the researchers themselves who wish to promote projects in different lines of study.

In the current scenario, where work is being done to find more effective antibiotics, more effective vaccines or new pharmacological products, pharmacists are obliged to update their knowledge and keep abreast of the latest developments in clinical trials. Faced with this reality, this academic institution has created this Hybrid Master's Degree MBA in Clinical Trial Management and Monitoring, where the graduate will spend 12 months in an advanced and intensive program, developed by an excellent team of professionals specialized in this field.

Thus, during this academic course, the professional will have access to a syllabus that offers a theoretical-practical perspective on advances in drug development, bioethics, clinical trials and biostatistics. For this purpose, innovative multimedia teaching resources (video summary of each topic, videos in detail), essential readings and simulations of clinical case studies will be used.

An online program in its theoretical framework, which is complemented by a practical stay in a leading clinical research center. In this real scenario, together with other professionals in the field, the graduate will be able to directly apply the updated concepts and enhance their competencies in Clinical Trial Management and Monitoring.

In this way, the graduate will carry out a 3-week stay, where they will be able to integrate new methodologies, support research teams in their clinical trials, and, in short, obtain the most updated vision on team management and scientific methods used by the best professionals. A great opportunity to get an update in a specialized environment.

This **Hybrid Master's Degree MBA in Clinical Trial Management and Monitoring** contains the most complete and up-to-date scientific program on the market. Its most notable features are:

- 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 information on the procedures that are essential for professional practice
- Presentation of practical workshops on clinical trials
- Algorithm-based interactive learning system for decision-making in the presented clinical situations
- Practical guidelines on approaching clinical trials
- Its special emphasis on evidence-based medicine and research methodologies for the conduct of clinical trials
- All of this will be complemented by 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
- In addition, an internship in one of the best research centers in the world will be offered

TECH offers you an excellent opportunity to update your knowledge through the most advanced syllabus in Clinical Trial Management and Monitoring"

Take an intensive 3-week Postgraduate Certificate at a prestigious center and get the latest information on drug and medical device authorization procedures"

In this Master's Degree, of a professionalizing nature and blended learning modality, the program is aimed at updating pharmaceutical professionals who work 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 research practice, and the theoretical-practical elements will facilitate the updating of knowledge and allow decision making.

Thanks to its multimedia content developed with the latest educational technology, it will allow the pharmaceutical professional a situated and contextual learning, that is, a simulated environment that will provide an immersive learning programmed to train in real situations. This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise throughout the program. For this purpose, the students will be assisted by an innovative interactive video system created by renowned and experienced experts.

This Hybrid Master's Degree MBA will bring you up to speed with the latest developments in clinical trial protocols and coordination.

Update your knowledge through the Hybrid Master's Degree MBA with an advanced syllabus, available 24 hours a day, from any electronic device with an Internet connection.

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Why Study this Hybrid Master's Degree?

The implementation of a Clinical Trial to develop new advanced treatment solutions to treat different pathologies includes the most experienced scientific praxis and requires compliance with updated protocols in terms of bioethics and current regulations. In this sense, TECH, at the forefront of education, has designed this Hybrid Master's Degree MBA in Clinical Trial Management and Monitoring that confers the greatest specialization in terms of the requirements necessary for the initiation of drug research in humans, the variety of development and funding pathways for non-commercial research, patient monitoring and biostatistics.

Don't wait any longer and update your knowledge on Clinical Trial Management and Monitoring in a real and cutting-edge technological scenario, during 3 weeks"

1. Updating from the Latest Technology Available

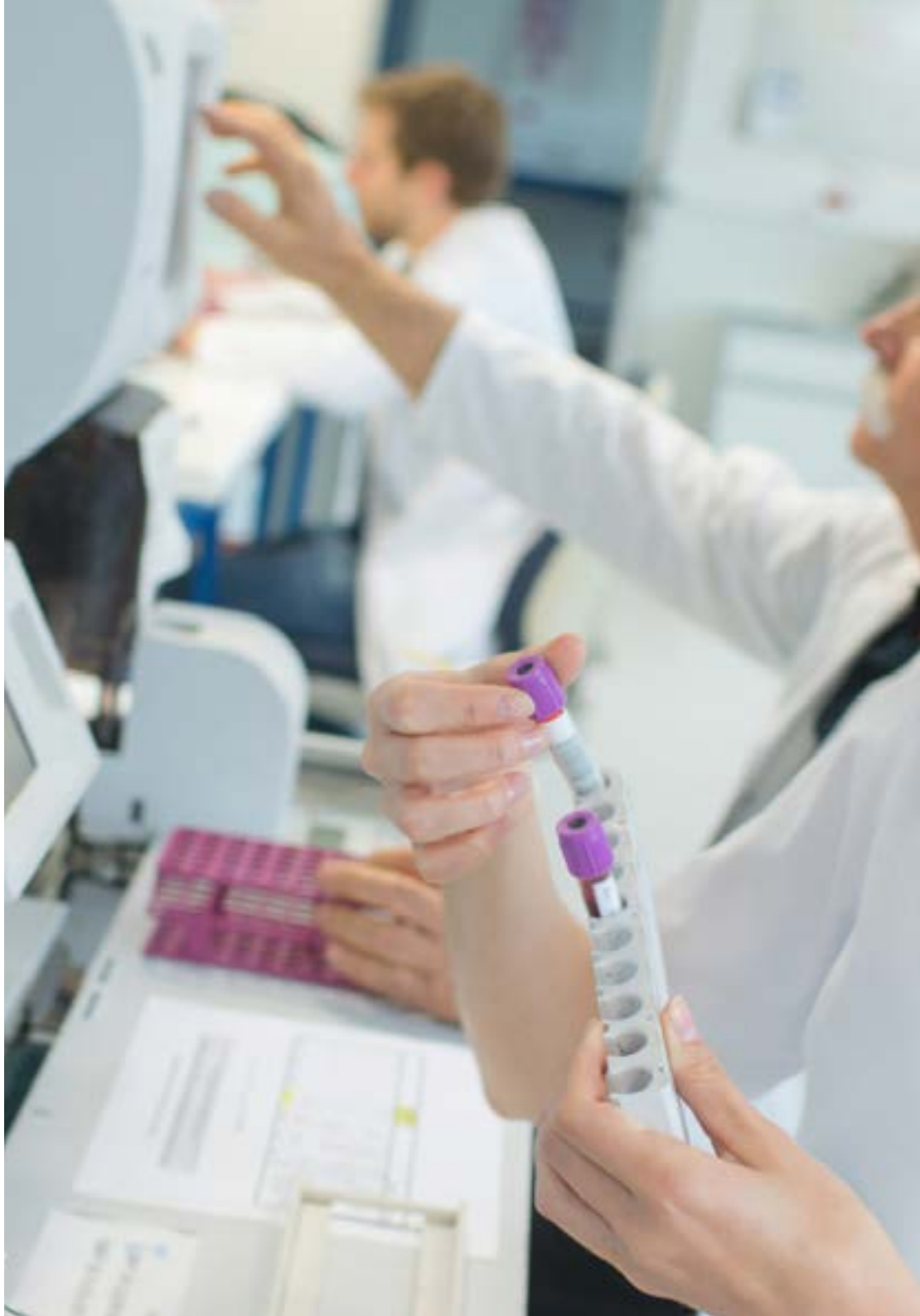
Increasing amounts of scientific and research data have given new impetus to Clinical Trial design. Biopharmaceutical companies have been adopting a number of strategies to innovate in trial design. For this reason, TECH, at the forefront of education, has developed this 100% practical space where professionals can update their practice and apply the latest developments in the sector, based on the latest technology available.

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

The large team of professionals that will accompany the specialist throughout the practical period is a first-class and an unprecedented guarantee of updating. With a specifically designated tutor, the student will be able to see real Clinical Trials in a state-of-the-art environment, which will allow him/her to incorporate new knowledge regarding the Management and Monitoring of these studies.

3. Enter into first-class scientific environments

TECH carefully selects all available centers for Internship Programs. Thanks to this, the specialist will have guaranteed access to a prestigious scientific environment in the area of Clinical Trials. In this way, you will be able to see the day-to-day work of a demanding, rigorous and exhaustive sector, always applying the latest theses and scientific postulates in its work methodology.



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

Thanks to TECH, professionals have the possibility of updating their curricular profile with useful and dynamic training, adjusted to the reality of the current market and the needs of society. For this reason, it offers this 100% practical program that will allow you to take the lead in clinical trials as part of a multidisciplinary team.

5. Expanding the Boundaries of Knowledge

TECH offers the possibility of doing this Internship Program, not only in national, but also in international centers. In this way, the professional will be able to expand his or her frontiers and catch up with the best in his or her sector, who come from different continents. A unique opportunity that only TECH could offer.

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

03

Objectives

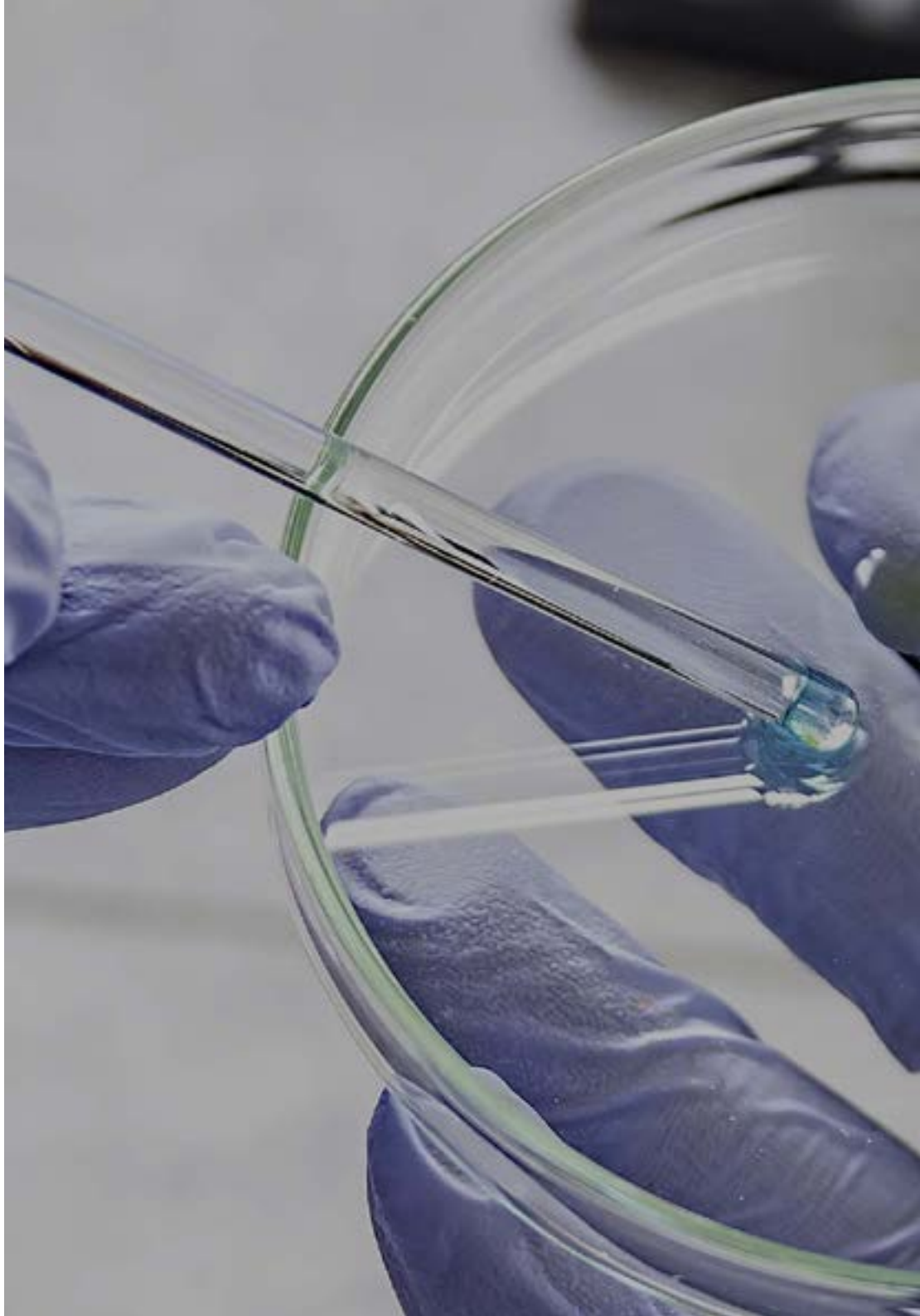
The design of the program of this Hybrid Master's Degree will lead the professional to acquire a complete update of their knowledge on the Management and Monitoring of Clinical Trials. For this purpose, TECH provides the most avant-garde pedagogical tools, which will allow the graduate to keep abreast of the latest developments in this field. In addition, the teaching team that integrates this program will guide the professional to successfully complete this program.

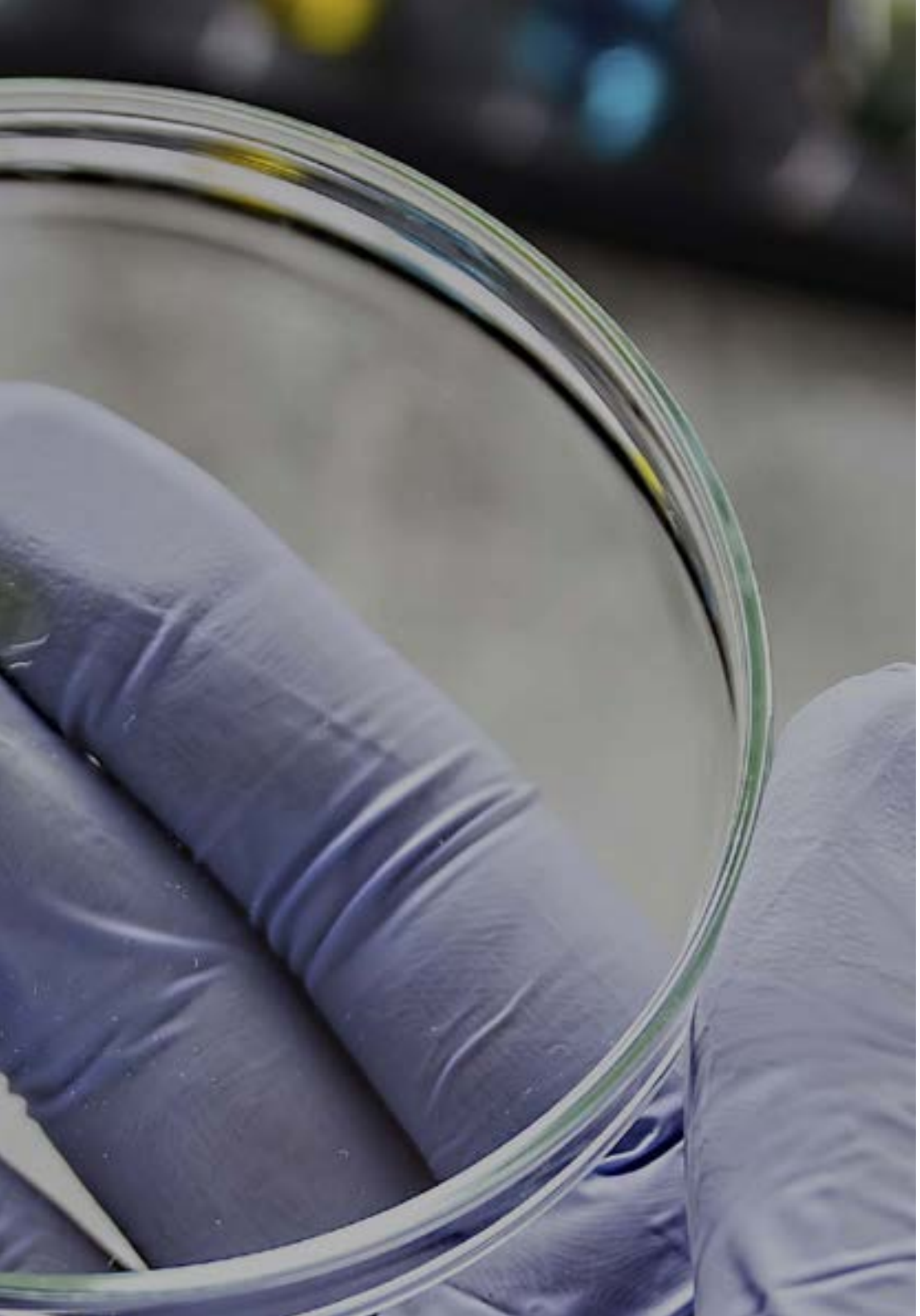
You have an excellent opportunity to broaden your skills through a flexible university program tailored to pharmacists"

General Objective

- This program has been designed for the professional to obtain, in only 12 months, the most relevant information on clinical trials, their monitoring and team management in this area. This will be possible thanks to a theoretical-practical approach, with which the graduate will be able, on the one hand, to have access to clinical case studies and, on the other hand, to be updated on the latest techniques and methods, through the Internship Program. In this way, the graduate will obtain an advanced and quality education

This program will lead you to master the most recent methods to be able to perform, with the highest scientific rigor, Clinical Trials"





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 medication
- Define the specific regulation of some drugs (biosimilars, advanced therapies)
- Define the use in special situations and their types
- Examine the process of financing a drug
- Specify strategies for the dissemination of research results
- Present how to read scientific information critically
- Compile sources of information on drugs and their types

Module 2. Clinical Trials I

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

Module 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 from the standpoint and with the participation of the hospital pharmacist
- Compile the specific characteristics of clinical trials in children and adolescents from a legal point of view
- Detail informed consent
- Know the physiological differences between children and adults

Module 4. Module 4. Bioethics and Regulations

- Develop the basic principles and ethical norms that regulate biomedical research
- 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 Good Clinical Practice Standards and their correct application
- Analyze the current European legislation on clinical trials
- Establish procedures for the authorization of drugs and medical devices
- Present the role and structure of clinical research ethics committees

Module 5. Monitoring of Clinical Trials I

- Specify both the professional profile of the clinical trial monitor and the skills that must be developed to carry out the monitoring process of a clinical trial
- Establish your responsibility in the selection of the center and in the initiation of the study
- Justify the importance of the monitor in ensuring the correct compliance with the procedures and activities established by the protocol and the standards of good clinical practice during the trial
- Build knowledge on the practical aspects of visits prior to the start of the clinical trial
- Detail 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 (SOP) at each stage of the clinical trial
- Present a data collection notebook and specify how to keep it up-to-date
- Establish the data collection process to assess safety in a clinical trial, considering Adverse Events (AE) and Serious Adverse Events (SAE)
- 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 within their center, following 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

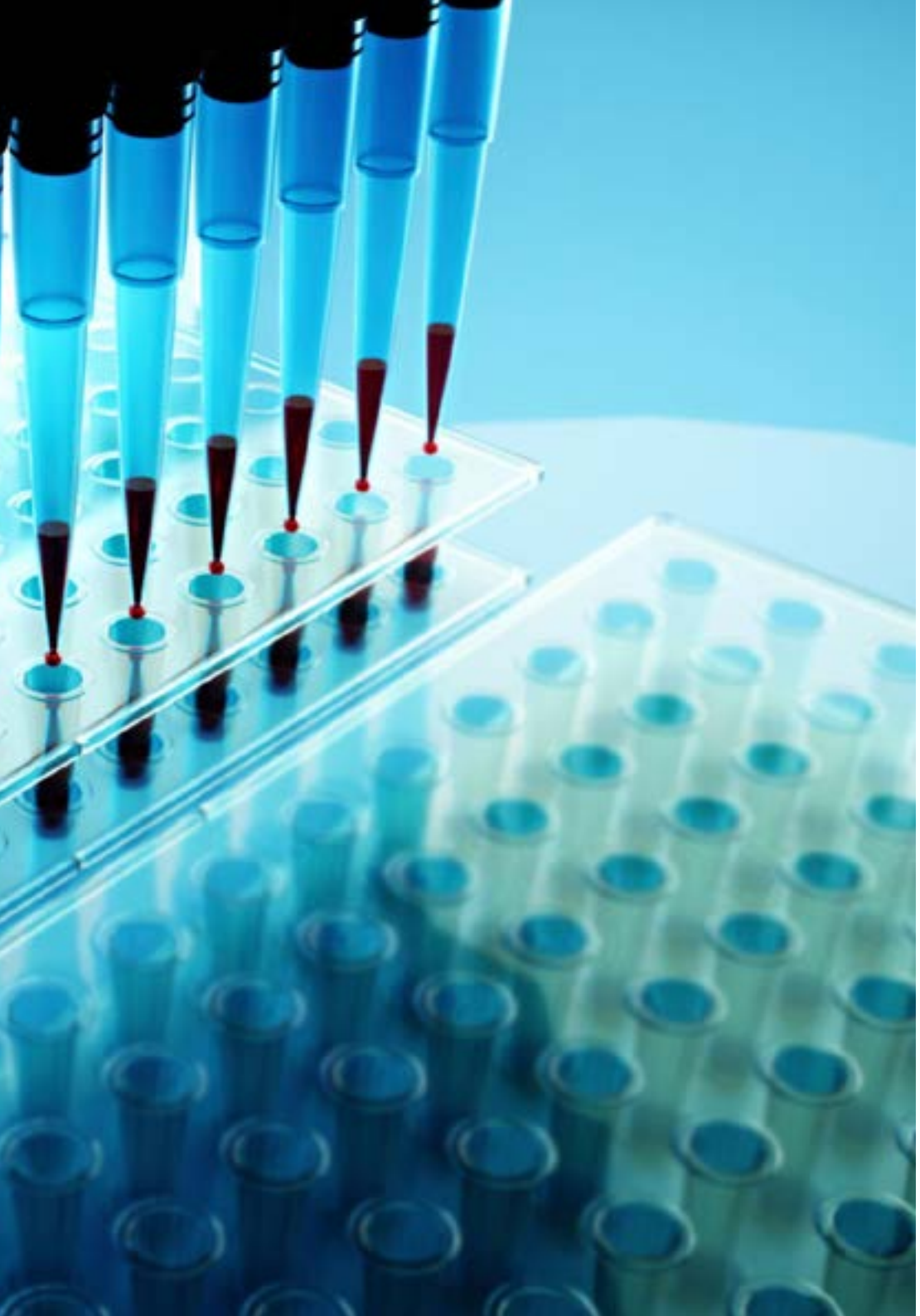
in a clinical trial (placebo, biologic) and their management

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 that intervene 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



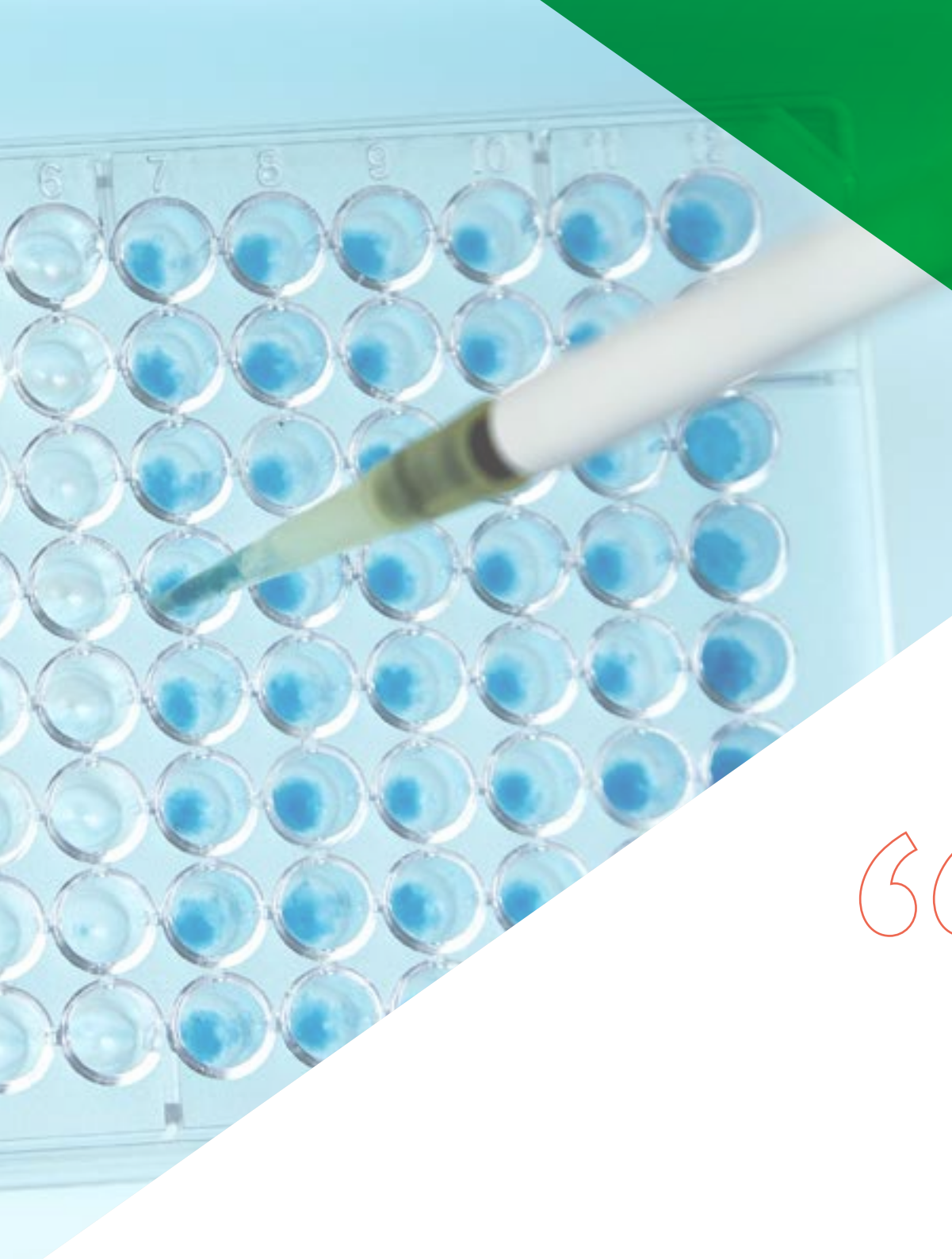
- Communicate and transmit statistical results correctly, through the preparation of reports
- Acquire an ethical and social commitment

This program will lead you to master the most recent methods to be able to perform, with the highest scientific rigor, Clinical Trials"

04

Competencies

This Hybrid Master's Degree provides an answer to those pharmaceutical professionals who are looking for a high quality program that enhances their leadership skills and research capabilities. Thus, at the end of this program, the graduate will have broadened his or her competencies in the field of Clinical Trial Management and Monitoring.



Through this program you will enhance your skills and abilities to lead research projects that study the creation of new drugs"

General Skills

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

You will combine theory and professional practice through a demanding and rewarding educational approach"

Specific Skills

- Publish research results in different formats
- Read scientific publications critically
- Know the legislation that regulates each of the steps involved in the development and authorization of a drug
- 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

05

Course Management

The professional who enters this Hybrid Master's Degree will have at his disposal a management and teaching staff with extensive experience in the field of research. This current knowledge is reflected in a syllabus, to which students will have access 24 hours a day. In addition, their human quality and proximity will allow the graduate to resolve any doubts that may arise during the course of this program.

You have a management and teaching staff made up of a team of professionals with extensive experience in Clinical Trials in leading hospitals"

Management

Dr. Vicente Gallego Lago

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

Professors

Ms. Ana Benito Zafra

- 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. 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

Dr. 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. Diana De Torres Pérez
- 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. 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

Dr. Mónica Dompablo Tobar
- Researcher at the Psychiatry Department of the Hospital Universitario 12 de Octubre
- Doctorate in Psychology the Complutense University of Madrid
- Degree in Psychology from the Universidad Autónoma de 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

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

Ms. Paloma Jiménez Fernández
- 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 Monitoring and Management of Clinical Trials from the Autonomous University of Madrid

Ms. Cristina Martín-Arriscado Arroba

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

Dr. Guillermo Moreno Muñoz

- 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)

Dr. Marcos Nieves Sedano

- Specialist in Oncohematological Clinical Trials at the HU 12 de Octubre
- FEA of the Neurology Service at the 12 de Octubre University Hospital
- Specialist in the Intensive Care Medicine Service at the 12 de Octubre University Hospital
- Research pharmacist in the Pharmacy Service of the 12 de Octubre University Hospital
- Degree in Pharmacy

Ms. Nuria Ochoa Parra

- Coordinator of clinical studies in the Cardiology Department of the 12 de Octubre 12 de 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

Dr. María del Mar Onteniente Gomis

- Clinical Trials Coordinator at the Dermatology Unit of Hospital 12 de Octubre
- 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 Seville

Ms. Carla Pérez Indigua

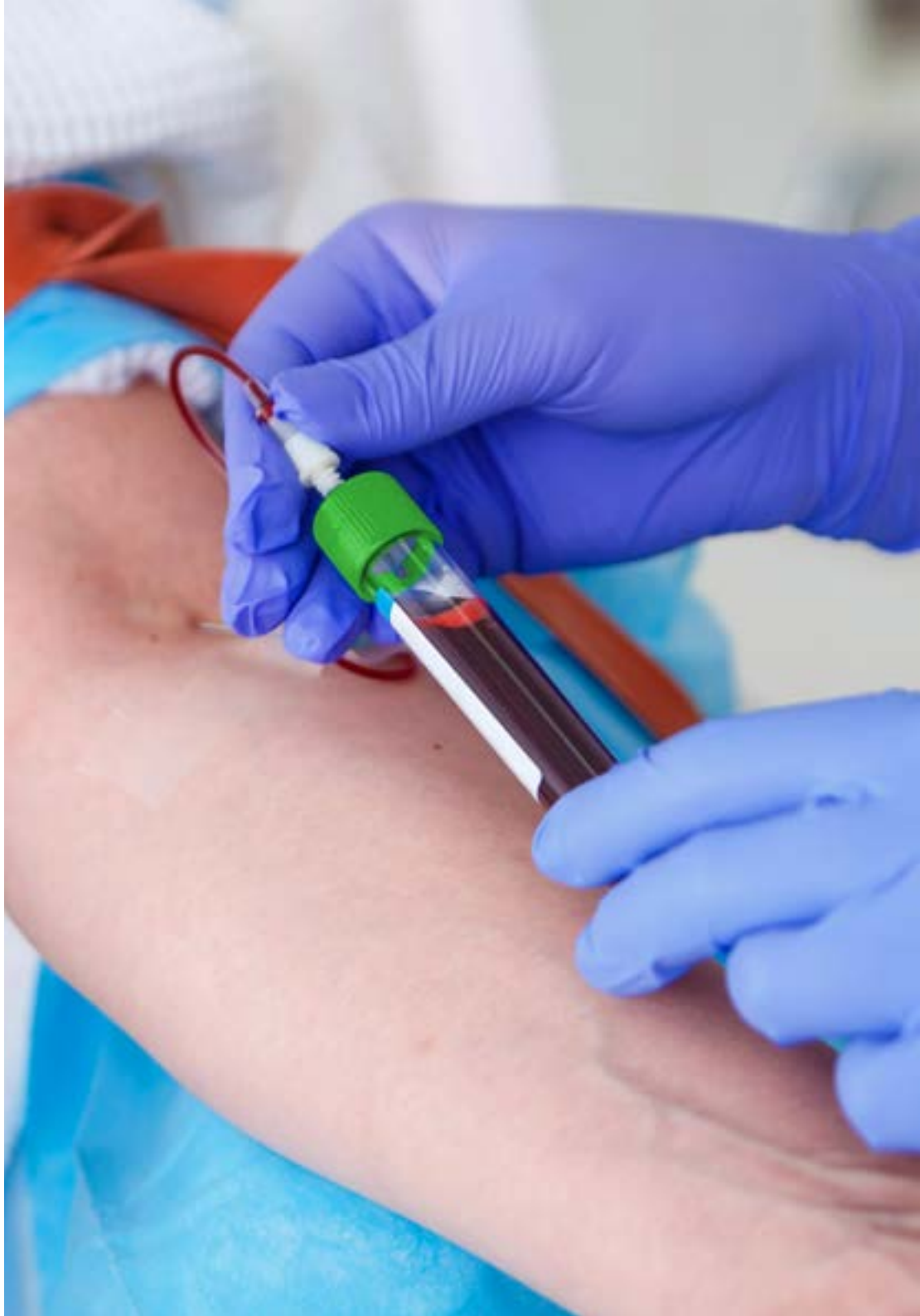
- Research Nurse in the Clinical Pharmacology Service of the San Carlos Clinical Hospital
- Nurse Coordinator of Phase I research studies in Oncology at The START Center for Cancer Care
- Nurse of hospitalization of the Obstetrics service of SERMAS
- Professor of the subject "Ethics of research with human beings" at UCM
- PhD 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

Dr. Roberto Rodríguez Jiménez

- 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
- Degree in Medicine and Surgery from the Autonomous University of Madrid
- Degree in Psychology, UNED
- Master's Degree in Psychotherapy, Autonomous University of Madrid
- Specialist in Alcoholism, Autonomous University of Madrid

Dr. Pablo Rojo Conejo

- Head of the Pediatric Infectious Diseases Section at the 12 de Octubre University Hospital
- WHO Scientific Advisor on Pediatric HIV
- Principal investigator and coordinator of the EMPIRICAL Project
- Author of numerous national and international specialized publications
- PhD in Medicine from the Complutense University of Madrid
- Degree in Medicine from the Complutense University of Madrid
- Member of: Board of Directors of the Spanish Society of Pediatric Infectious Diseases, Board of Directors of the European Society of Infectious Diseases, Scientific Committee of the European Network of Pediatric Infectious Diseases, Scientific Committee of the Spanish Pediatric HIV Network, Scientific Advisory Committee on Pediatric COVID-19



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. Sánchez Ostos, Manuel

- 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

Dr. Andrea Valtueña Murillo

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

Ms. Montserrat Cano Armenteros

- 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
- Professor in postgraduate university studies
- Degree in Biology by the University of Alicante
- Master's Degree in Clinical Trials from the University of Seville
- 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

The teaching staff of this Hybrid Master's Degree is made up of renowned professionals who contribute their experience in each area of study"

06

Educational Plan

The syllabus for this program has been developed to provide the most relevant and up-to-date information on Clinical Trial Management and Monitoring. For this purpose, the professional will be provided with didactic resources, which will lead them to enter in a dynamic way into the research and development of drugs, the advances in the techniques and methods used in Clinical Trials, as well as the follow-up of the patient. In addition, thanks to the Relearning system, the graduate will be able to reduce the long hours of study and memorization. Once this phase is completed, the professional will enter an Internship Program, where he/she will directly expand his/her knowledge.

A study plan designed to offer you, in 12 months, the most advanced and recent content on Clinical Trial Management and Monitoring"

Module 1. Drug research and development

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

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

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

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

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

1.6. Pharmacovigilance
  1.6.1. Pharmacovigilance in Development
  1.6.2. Pharmacovigilance in Marketing Authorization
  1.6.3. Post-Authorization Pharmacovigilance
1.7. Uses in Special Situations
  1.7.1. Introduction
  1.7.2. Regulations BORRAR
  1.7.3. Examples:
1.8. From Authorization to Commercialization
  1.8.1. Introduction
  1.8.2. Drug Financing
  1.8.3. Therapeutic Positioning Reports
1.9. Special Forms of Regulation
  1.9.1. Advanced Therapies
  1.9.2. Accelerated Approval
  1.9.3. Biosimilars
  1.9.4. Conditional Approval
  1.9.5. Orphan Drugs
1.10. Dissemination of Research
  1.10.1. Scientific Article
  1.10.2. Types of Scientific Articles
  1.10.3. Quality of Research *Checklist*
  1.10.4. Drug Information Sources

Module 2. Clinical Trials (I)

2.1. Clinical Trials. Fundamental Concepts I
  2.1.1. Introduction
  2.1.2. Definition of Clinical Trial (CT)
  2.1.3. History of Clinical Trials
  2.1.4. Clinical Research
  2.1.5. Parties Involved in CTs
  2.1.6. Conclusions
2.2. Clinical Trials. Fundamental Concepts II
  2.2.1. Standards of Good Clinical Practice
  2.2.2. Clinical Trial Protocol and Annexes
  2.2.3. Pharmacoeconomic Assessment
  2.2.4. Aspects that Could Be Improved in Clinical Trials
2.3. Clinical Trials Classification
  2.3.1. Clinical Trials 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. Non-commercial Research
- 2.5.3. Start-up of Non-commercial Clinical Trials
- 2.5.4. Difficulties of the Independent Promoter
- 2.5.5. Promotion of Independent Clinical Research
- 2.5.6. Application for Grants for Non-commercial Clinical Research
- 2.5.7. 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. Ethical aspects
  - 2.6.1.10. 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. Ethical aspects
- 2.8.13. Information and Consent
- 2.8.14. Financing and Insurance
- 2.8.15. Publication Policy
- 2.8.16. 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
3.1.5.1. Medical Prescription Validation
3.1.5.2. Dispensing
3.1.5.2.1. Dispensing Procedure
3.1.5.3. Checking Storage Conditions and Expiration Date
3.1.5.4. Dispensing Act
3.1.5.5. 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. Current Legislation Regulations
3.2.1.3. 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
3.3.5.1. Situation of the Hospital Pharmacy Service (HPS) and CT Units BORRAR
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. Researchers Obligations BORRAR
  - 3.5.4.1. Regulatory Compliance and Ethics
  - 3.5.4.2. 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. (SUSAR)
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 BORRAR

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
  - 4.5.2.9. Insurance and Financial Compensation
    - 4.5.2.9.1. Safety
    - 4.5.2.9.2. Indemnification
    - 4.5.2.9.3. Compensation
- 4.5.3. Confidentiality
- 4.5.4. Violations
- 4.5.5. Continuation of Treatment After the Trial
- 4.5.6. 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. European Legislation
- 4.7.3. FDA, EMA and AEMPS
- 4.7.4. Communication
- 4.7.5. 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. Promoter 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. The Monitor II
- 5.6.1. Monitors Responsibilities

5.7. Verification of Source Documents Source Documents Verification (SDV)

5.8. Monitors Report and Monitoring Letter
- 5.8.1. Selection Visit
  - 5.8.1.1. Researcher Selection
  - 5.8.1.2. Aspects to take into account
  - 5.8.1.3. Suitability of Facilities
  - 5.8.1.4. Visit to other Hospital Services
  - 5.8.1.5. Deficiencies in Study Facilities and Staffing
- 5.8.2. Start Up in a clinical research center
  - 5.8.2.1. Definition and Functionality
  - 5.8.2.2. 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. Initial Visit in Hospital Pharmacy
- 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 SAE
  - 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
- 6.1.4. Samples
  - 6.1.4.1. Local and Central
  - 6.1.4.2. Types
  - 6.1.4.3. Temperature Registration
  - 6.1.4.4. Calibration/Maintenance Certificate
  - 6.1.4.5. Meeting with the Research Team
    - 6.1.4.5.1. Signature of Pending Documentation
    - 6.1.4.5.2. Discussion of Findings
    - 6.1.4.5.3. Retraining
    - 6.1.4.5.4. Corrective Actions
  - 6.1.4.6 Review of ISF *(Investigator Site File)*
    - 6.1.4.6.1. Clinical Investigations (CIs) and Protocols
    - 6.1.4.6.2. New Approvals from the Ethics Committee and the AEMPS
    - 6.1.4.6.3. LOG
    - 6.1.4.6.4. Site Visit Letter
    - 6.1.4.6.5. New Documentation
  - 6.1.4.7 Suspected Unexpected Serious Adverse Reactions (SUSARs)
    - 6.1.4.7.1. Concept
    - 6.1.4.7.2. Principal Investigator Review
  - 6.1.4.8. Electronic Notebook

6.2. *Close-Out Visit*
- 6.2.1. Definition
  - 6.2.1.1 Reasons for Close-Out Visits
    - 6.2.1.1.1. Completion of the Clinical Trial
    - 6.2.1.1.2. Not Complying with Protocol
    - 6.2.1.1.3. Not Complying with Good Clinical Practices
    - 6.2.1.1.4. At the Investigators Request
    - 6.2.1.1.5. Low Recruitment
- 6.2.2. Procedures and Responsibilities
  - 6.2.2.1 Before the Close-Out Visit
  - 6.2.2.2 During the Close-Out Visit
  - 6.2.2.3 After the Close-Out Visit
- 6.2.3. Pharmacy Close-Out Visit
  - 6.2.3.1 Final Report
  - 6.2.3.2 Conclusions

6.2.4. *"Queries* Management", Database Slicing
6.2.4.1. Definition
6.2.4.2. *Queries* Rules
6.2.4.3. How are "Queries" generated?
6.2.4.4. Automatically
6.2.4.5. By the Monitor
6.2.4.6. By an External Reviewer
6.2.5. When are *"Queries"* Generated?
6.2.5.1. After a Monitoring Visit
6.2.5.2. Close to Closing a Database
6.2.5.3. *Query* Status
6.2.5.4. Open
6.2.5.5. Pending Revision
6.2.5.6. Closed
6.2.5.7. Database Slicing
6.2.5.8. Most Frequent Database Slicing Errors
6.2.5.9. Conclusions
6.3. AE Management and SAE Notification
6.3.1. Definitions
6.3.1.1. Adverse Events *Adverse Event* (AE)
6.3.1.2. Adverse Reactions (AR)
6.3.1.3. *Serious Adverse Event* (SAE) or Serious Adverse Reaction (SAR)
6.3.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR) (SUSAR)

6.3.2. Data to be Collected by the Researcher
6.3.2.1. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
6.3.2.2. Description
6.3.2.2.1. Dates
6.3.2.2.2. Unraveling
6.3.2.2.3. Intensity
6.3.2.2.4. Actions Taken
6.3.2.2.5. Causality Relationship
6.3.2.2.6. Basic Questions
6.3.2.3. Who notifies, what is notified, to whom is it notified, how is it notified, when is it notified?
6.3.2.3.1. Procedures for the communication of AA/RA with investigational drugs
6.3.2.3.2. Expedited Notification of Individual Cases
6.3.2.3.3. Periodic Security Reports
6.3.2.3.4. "Ad hoc" Security Reports
6.3.2.3.5. Annual Reports
6.3.2.4. Special Interest Events
6.3.2.5. Conclusions

6.4. Clinical Research Associate (CRA) Standard Operating Procedures
Standard Operating Procedures (SOP)
6.4.1. Definition and objectives
6.4.1.1. Writing a SOP
6.4.1.2. Procedure
6.4.1.3. Format
6.4.1.4. Implementation
6.4.1.5. Review
6.4.2. SOP *Feasibility* and *Site Qualification Visit*
6.4.2.1. Procedures
6.4.2.2. Visit home
6.4.2.3. Procedures Prior to the Initiation Visit
6.4.2.4. Procedures During the Initiation Visit
6.4.2.5. Monitoring Initiation Visit Procedures
6.4.3. Monitoring Visit
6.4.3.1. Procedures Prior to the Monitoring Visit
6.4.3.2. Procedures During the Monitoring Visit
6.4.3.3. Monitoring Letter
6.4.4. SOP for Close-Out Visit
6.4.4.1. Preparing the Close-Out Visit
6.4.4.2. Manage the Close-Out Visit
6.4.4.3. Monitoring After a Close-Up Visit
6.4.5. Conclusions

6.5. Quality Guarantee Audits and Inspections
6.5.1. Definition
6.5.2. Types of Audits
6.5.2.1. Internal Audits
6.5.2.2. External Audits or Inspections
6.5.3. How to Prepare an Audit
6.5.3.1. Principal *Findings*
6.5.4. Conclusions

6.6. Protocol Deviations
6.6.1. Criteria
6.6.1.1. Non-Compliance with Inclusion Criteria
6.6.1.2. Compliance with Exclusion Criteria
6.6.2. International Classification of Functioning (ICF) Deficiencies
6.6.2.1. Correct Signatures on Documents (CI, LOG)
6.6.2.2. Correct Dates
6.6.2.3. Correct Documentation
6.6.2.4. Correct Storage
6.6.2.5. Correct Version

6.7. Out-Of-Window Visits
6.7.1. Poor or Wrong Documentation

6.7.2. The 5 Rights Medication Administration
6.7.2.1. Right Patient
6.7.2.2. Right Drug
6.7.2.3. Right Time
6.7.2.4. Right Dose
6.7.2.5. Right Route
6.8. Missing Samples and Parameters
6.8.1. Missing Samples
6.8.2. Parameter Not Performed
6.8.3. Sample Not Sent On Time
6.8.4. Time of Sample Collection
6.8.5. Request for Kits Out of Time
6.8.6. Information Privacy
6.8.6.1. Information Security
6.8.6.2. Reporting Security
6.8.6.3. Photo Security
6.8.7. Temperature Deviations
6.8.7.1. Register
6.8.7.2. Inform
6.8.7.3. Act
6.8.8. Open Blinding at the Wrong Time
6.8.9. PI Availability
6.8.9.1. Not Updated in Interactive Voice Response Services (IVRS)
6.8.9.2. Not Sent on Time
6.8.9.3. Not Registered on Time
6.8.9.4. Broken Stock
6.8.10. Forbidden Medication
6.8.11. Key and Non-Key
6.9. Source and Essential Documents
6.9.1. Features
6.9.2. Source Documents Location
6.9.3. Source Document Access
6.9.4. Source Document Types
6.9.5. How to Correct a Source Document
6.9.6. Source Document Retention Time
6.9.7. Main Components of the Medical History
6.9.8. Investigator's Brochure (IB)
6.10. *Monitoring Plan*
6.10.1. Visits
6.10.2. Frequency (F)
6.10.3. Organisation
6.10.4. Confirmation
6.10.5. *Site Issues* Categorization
6.10.6. Communication with Researchers
6.10.7. Research Team Training
6.10.8. *Trial Master File*
6.10.9. Reference Documents
6.10.10. Electronic Notebooks Remote Review
6.10.11. *Data Privacy*
6.10.12. Center Management Activities
6.11. Data Collection Notebooks
6.11.1. Concept and History
6.11.2. Timeline Compliance
6.11.3. Data Validation
6.11.4. Management of Data Inconsistencies or *"Queries"*
6.11.5. Data Exports
6.11.6. Security and Roles
6.11.7. Traceability and Logs
6.11.8. Report Generation
6.11.9. Notifications and Alerts
6.11.10. 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
- 8.1.2. Principal Investigator
- 8.1.3. Sub-Investigator
- 8.1.4. Coordinator
- 8.1.5. Rest of the Team

8.2. Responsibilities of the Research Team
- 8.2.1. Compliance with Good Clinical Practices and Current Legislation
- 8.2.2. Compliance of the Study Protocol
- 8.2.3. Care and Maintenance of the Research Archive

8.3. Task Delegation
- 8.3.1. Document Details
- 8.3.2. Example

8.4. Trial Coordinator
- 8.4.1. Responsibilities
  - 8.4.1.1. Primary Responsibilities
  - 8.4.1.2. Secondary Responsibilities
- 8.4.2. Capabilities and Competencies
  - 8.4.2.1. Academic Background
  - 8.4.2.2. Competencies
- 8.4.3. Clinical Trials vs. Observational Study
  - 8.4.3.1. Types of Clinical Trials
  - 8.4.3.2. Types of Observational Studies

8.5. Protocol
- 8.5.1. Primary and Secondary Objectives
  - 8.5.1.1. What Are They and Who Defines Them?
  - 8.5.1.2. Importance During the Course of the Clinical Trial
- 8.5.2. Inclusion and Exclusion Criteria
  - 8.5.2.1. Inclusion Criteria
  - 8.5.2.2. Exclusion Criteria
  - 8.5.2.3. Example
- 8.5.3. Flowchart
  - 8.5.3.1. Document and Explanation
- 8.5.4. Concomitant Medication and Prohibited Medication
  - 8.5.4.1. Concomitant Drug
  - 8.5.4.2. Forbidden Medication
  - 8.5.4.3. Washout Periods
- 8.5.5. Documentation Required to Initiate Clinical Trial
  - 8.5.5.1. Curriculum of the Research Team
  - 8.5.5.2. Basic Notions of a Research Curriculum
  - 8.5.5.3. Good Clinical Practice Example
- 8.5.6. Good Clinical Practice
  - 8.5.6.1. Origin of Good Clinical Practices
  - 8.5.6.2. How to Get Certified?
  - 8.5.6.3. Expiration
- 8.5.7. Suitability of the Research Team
  - 8.5.7.1. Who Signs the Document?
  - 8.5.7.2. Presentation to Ethics Committee
- 8.5.8. Suitability of Facilities
  - 8.5.8.1. Who Signs the Document?
  - 8.5.8.2. Ethical Committee Presentation
- 8.5.9. Calibration Certificates
  - 8.5.9.1. Calibration
  - 8.5.9.2. Calibration Equipment
  - 8.5.9.3. Valid Certifications
  - 8.5.9.4. Expiration
- 8.5.10. Other *Training*
  - 8.5.10.1. Necessary Certifications According Protocol
- 8.5.11. Main Functions Trial Coordinator
  - 8.5.11.1. Documentation Preparation
  - 8.5.11.2. Documentation Requested for Approval of the Study at the Center

8.5.12. *Investigator Meeting*
8.5.12.1 Importance
8.5.12.2 Attendees
8.5.12.3 Initiation Visit
8.5.12.3.1. Duties of the Coordinator
8.5.12.3.2. Functions of the Principal Investigator and Subinvestigators
8.5.12.3.3. Promoter
8.5.12.3.4. Monitor
8.5.13. Monitoring Visit
8.5.13.1. Preparation After a Monitoring Visit
8.5.13.2. Functions During the Monitoring Visit
8.5.14. End-Of-Study Visit
8.5.14.1. 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
8.6.2. Identify the Responsibilities of the Investigation Team during the Visit
8.6.2.1. Visit Calculator
8.6.2.2. Preparation of Documentation to be Used During the Visit
8.7. Complementary Tests
8.7.1. Analysis
8.7.2. Chest X-Ray
8.7.3. Electrocardiogram
8.7.4. Calendar of Visits
8.7.5. Example
8.7.6. Samples
8.7.6.1 Equipment and Materials Necessary
8.7.6.1.1. Centrifuge
8.7.6.1.2. Incubator
8.7.6.1.3. Refrigerators
8.7.6.2 Processing of Samples
8.7.6.2.1. General Procedure
8.7.6.2.2. Example
8.7.6.3 Laboratory Kits
8.7.6.3.1. What are they?
8.7.6.3.2.Caducidad
8.7.6.4. Shipment of Samples
8.7.6.4.1. Sample Storage
8.7.6.4.2. Ambient Temperature Shipment
8.7.6.4.3. 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. Telephonics
  - 8.9.2.2. Electronics
- 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 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. Follow-Up of Adverse Reactions, and Symptom Management in the Study Medication Intake
- 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. Statistician 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. What is a Statistical Analysis Plan?
- 10.7.2. When to Perform the Statistical Analysis Plan
- 10.7.3. Statistical Analysis Plan Parts

10.8. Intermediate Analysis
- 10.8.1. Reasons for an Early Termination 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

Thanks to this program you will be up to date with the most effective methods used in Biostatistics"

07

Clinical Internship

Once the theoretical phase is completed, the professional will start a practical stay in a prestigious research center, which will allow them, in only 3 weeks, to update on the techniques, instruments and methodologies used for the management of research teams and Clinical Trials.

This academic institution carefully selects the research centers where you will stay, so that you will obtain a quality knowledge update"

The Internship Program of this MBA program in Clinical Trials Management and Monitoring consists of a 3-week practical training period, from Monday to Friday, in 8-hour consecutive days to update knowledge with a team of professionals with experience in this field. An excellent opportunity to expand and strengthen competencies in a 100% real research scenario, and in a reference research center.

Thus, during this period, the pharmaceutical professional will be able to see, first hand, the different techniques and instruments used in Clinical Trials, the current methods of patient follow-up, information storage protocols, as well as the relevance of bioethics and biostatistics in the creation of new drugs. An advanced knowledge, which you will achieve successfully, thanks to the specialized team that will tutor you and the support of TECH's teaching team, which will supervise the fulfillment of the objectives set.

This academic institution thus provides a Practical Internship Program, which not only complements the theoretical framework, but also offers a closer vision, where the graduate will be able to put into practice all the concepts addressed in depth in the syllabus. In addition, it will be carried out in a recognized center with a team of high-level professionals in the field of research and development of new drugs.

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 be the basis of the practical part of the training, and their implementation will be subject to the center's own availability and workload, the proposed activities being the following:

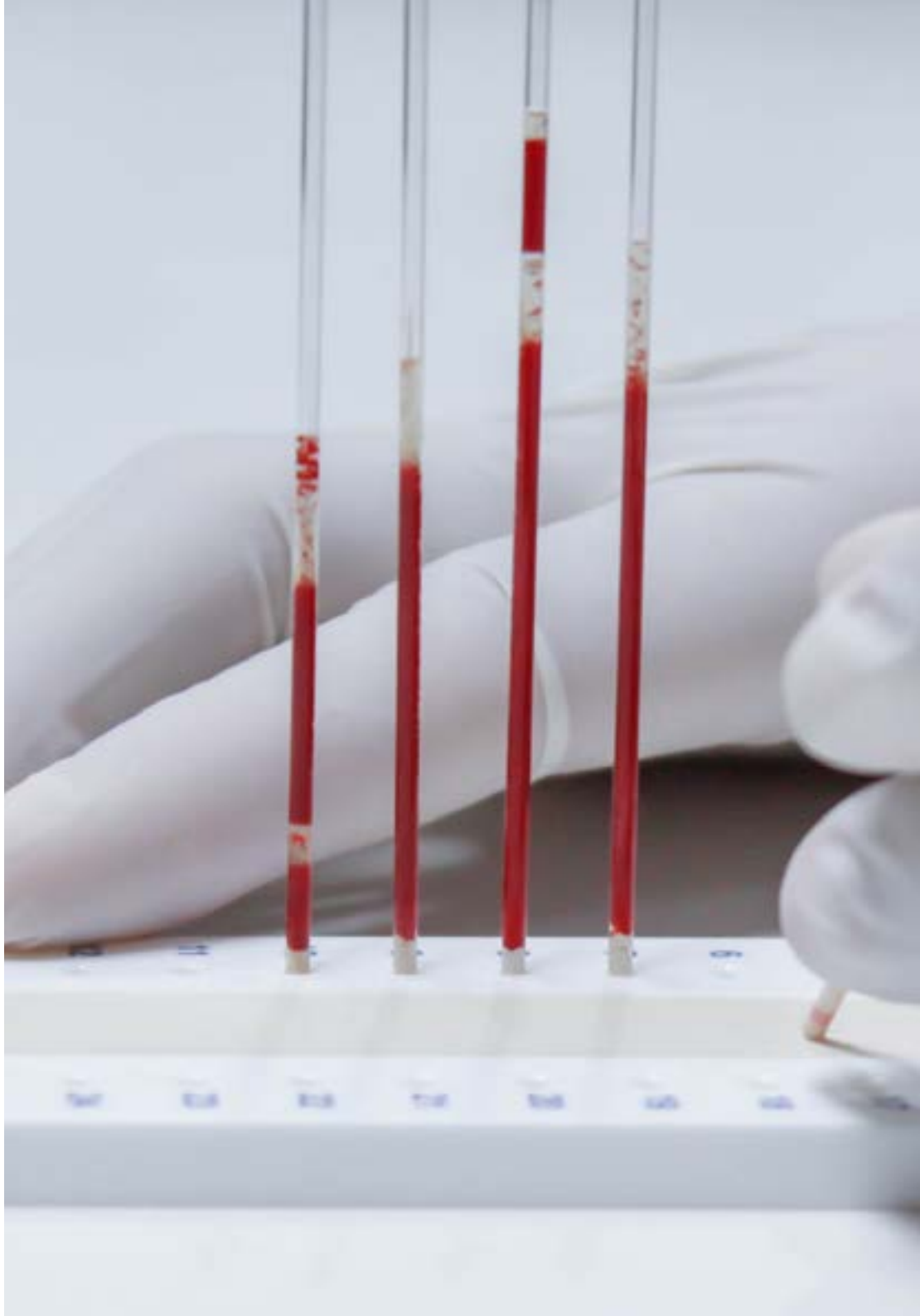
Module	Practical Activity
Drug research and development	Participate in the development of all phases of a Clinical Trial
	Identify and know how to use the different drugs that can be used in Clinical Trials
	Collect clinical trial data for further analysis
	Publish research results in different formats
Coordination of Clinical Trials	Provide support in the presentation of the documentation for the start-up of the Clinical Trial
	Identify all documents to be contained in the researcher's file and manage the file
	Participate in the communication of the results of the Clinical Trials through the most appropriate means in each case
	Manage and support the overall monitoring process
Bioethics and regulations in the development of clinical trials	Establish research protocols for Clinical Trials
	Provide support during the whole process of the Clinical Trials following the legislation in force on the matter
	Participate in the development of a safety surveillance plan for marketed drugs
	Recognize and comply with the rules governing Clinical Trials
Follow-up of patients in Clinical Trials	Follow up of patients participating in research
	Manage monitoring visits and closure of the Clinical Trial
	Collaborate in the evaluation of treatments and possible adverse effects caused by some drugs
	Participate in the development of Clinical Trials with the collaboration of the hospital pharmacist
	Ensure the safety of participants in Clinical Trials

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 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 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 Master's Degree will receive a certificate accrediting their stay at the center.

5. EMPLOYMENT RELATIONSHIP: The Hybrid 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 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.

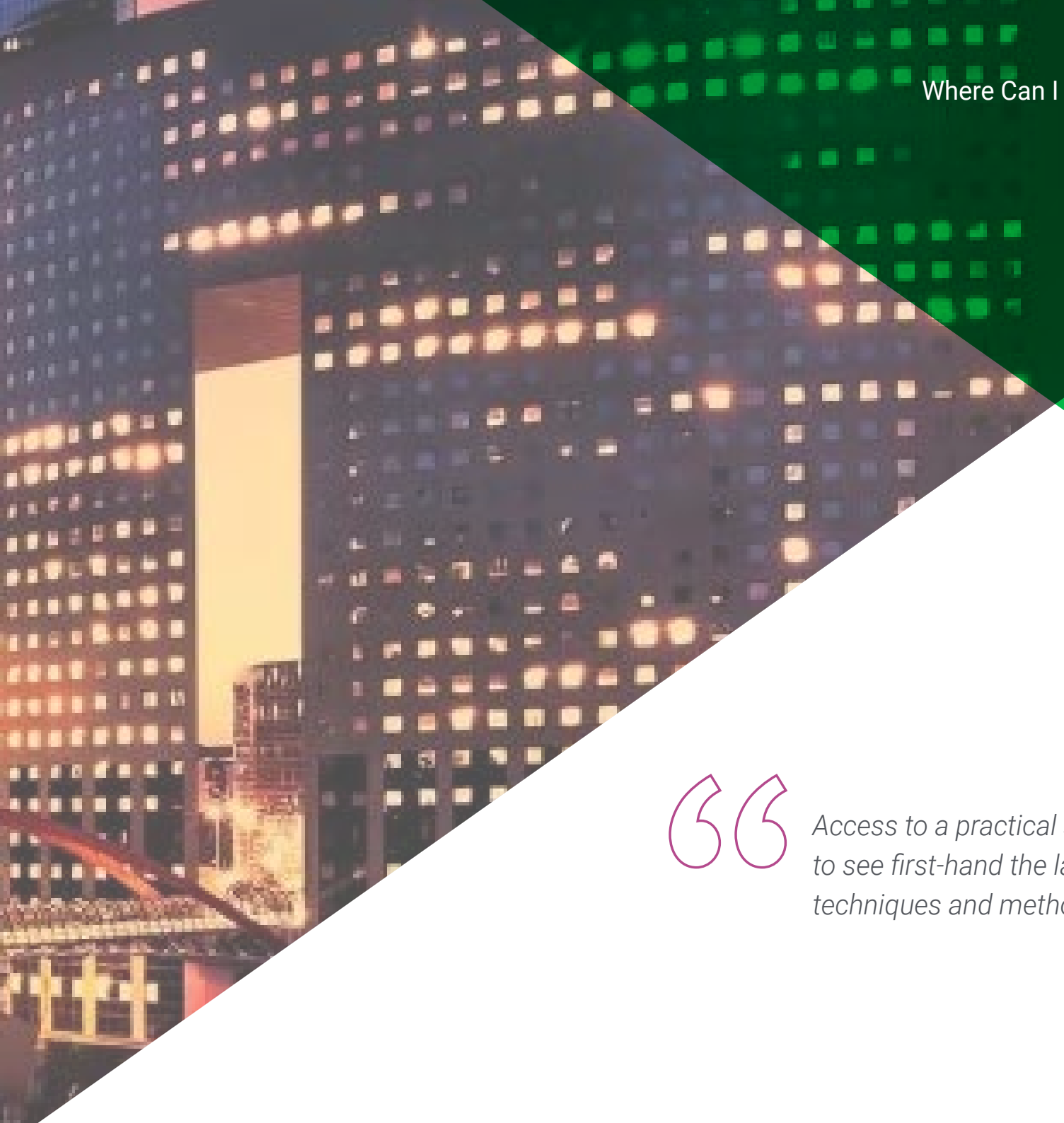
7. DOES NOT INCLUDE: The Hybrid Master's Degree will not include any element not described in the present conditions. Therefore, it does not include accommodation, transportation to the city where the internship takes place, visas or any other items not listed.

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?

This Hybrid Master's Degree program includes a practical internship in a leading research center. For its selection, TECH has taken into account its prestige, as well as the human and professional team that integrates it. All this, to offer a high level and quality education to all students who are part of this program.



Access to a practical stay, which will allow you to see first-hand the latest developments in the techniques and methods used in clinical trials"

The student will be able to complete the practical part of this Hybrid Master's Degree at the following centers:

Pharmacy

IdiPAZ

Country
Spain BORRAR

City
Madrid

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

La Paz University Hospital Research Institute

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

Histocell Regenerative Medicine

Country
Spain BORRAR

City
Vizcaya

Address: Parque Científico y Tecnológico de Bizkaia, edificio 801A-2ª planta. 48160-Derio, Bizkaia

Histocell Regenerative Medicine are experts in Cell and Biological Therapy Drug Production

Related internship programs:
- Management and Monitoring of Clinical Trials

Hospital Italiano La Plata

Country
Argentina

City
Buenos Aires

Address: Av. 51 Nº 1725 e/ 29 y 30 La Plata, Buenos Aires

Non-profit Community Center
for specialized clinical care

Related internship programs:
- Advanced Emergency Medicine
- Gynecologic Oncology

Make the most of this opportunity to surround yourself with expert professionals and learn from their work methodology"

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 be confronted with multiple simulated clinical cases based on real patients, in which they will have to investigate, establish hypotheses and ultimately, resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Pharmacists learn better, more quickly and more sustainably over time.

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

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

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

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

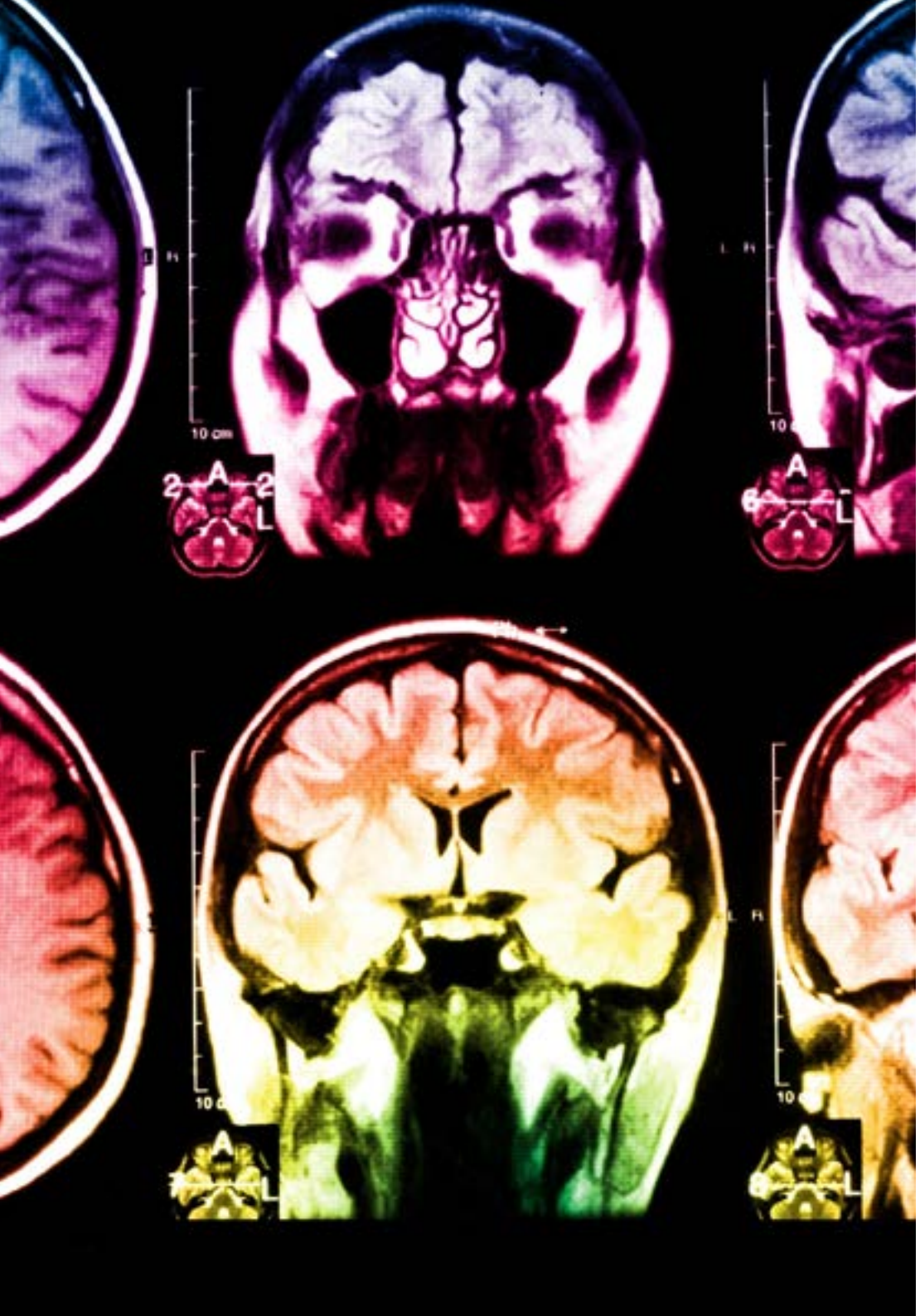
1. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts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

Relearning Methodology

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

Our University is the first in the world to combine the study of clinical cases with a 100% online learning system based on repetition, combining a minimum of 8 different elements in each lesson, which represent a real revolution with respect to simply studying and analyzing cases.

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



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

With this methodology, more than 115,000 pharmacists have been trained with unprecedented success in all clinical specialties, regardless of the surgical load. This pedagogical methodology is developed in a highly demanding environment, with a university student body with a high socioeconomic profile and an average age of 43.5 years.

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

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

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

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

Study Material

All teaching material is created specifically for the course by specialist pharmacists who will be teaching the course, so that the didactic development is highly specific and accurate.

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

Video Techniques and Procedures

TECH introduces students to the latest techniques, to the latest educational advances, to the forefront of current pharmaceutical care procedures. All of this, first hand, and explained and detailed with precision to contribute to assimilation and a better understanding. And best of all, you can watch them as many times as you want.

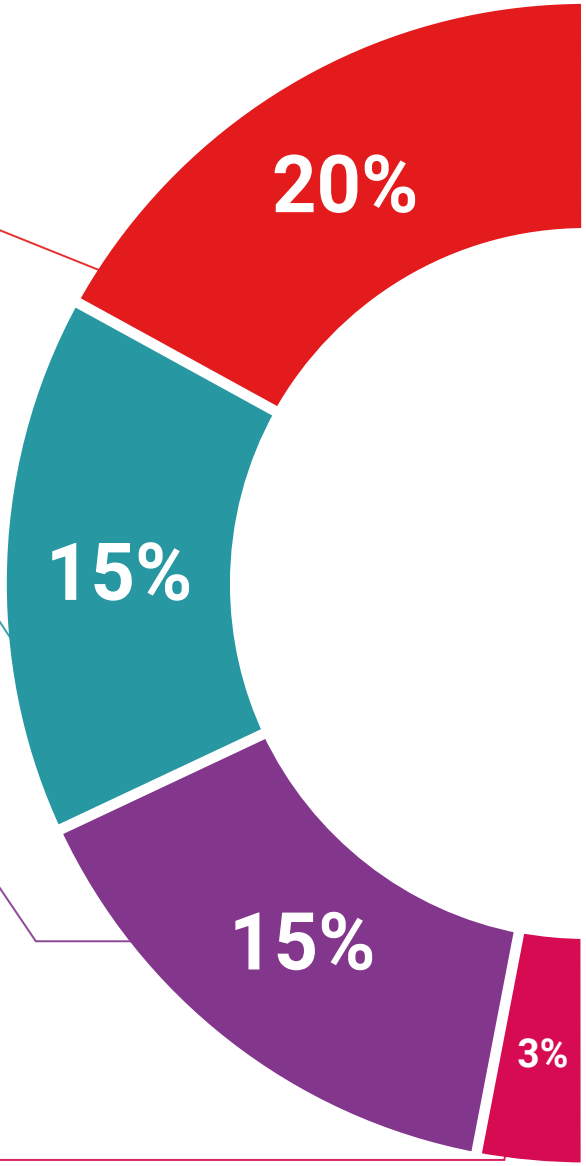
Interactive Summaries

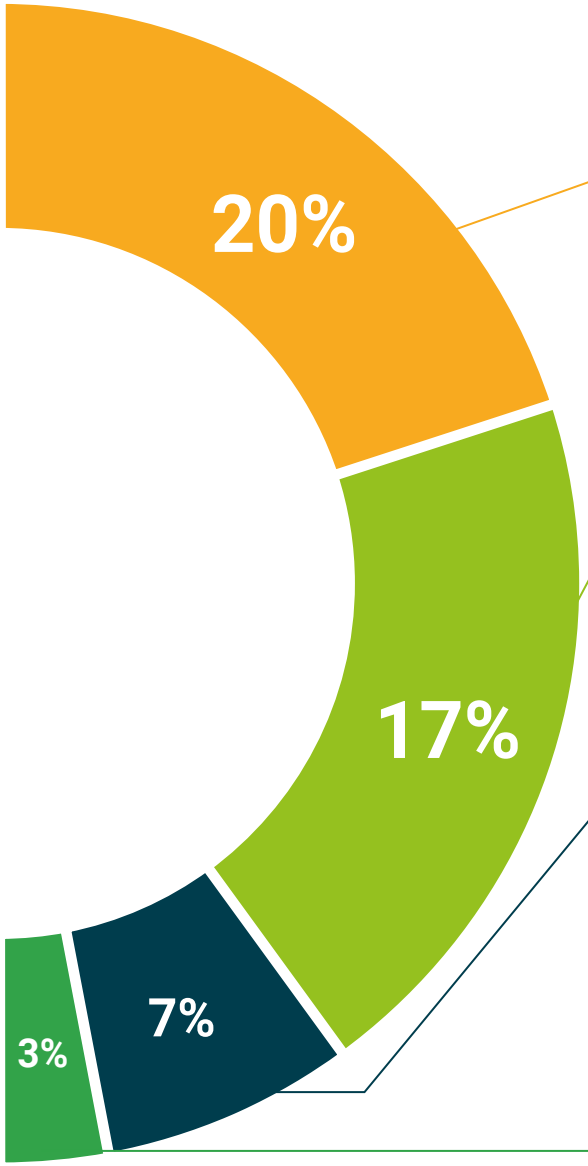
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

This unique multimedia content presentation training system was awarded by Microsoft as a "European Success Story".

Additional Reading

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





Expert-Led Case Studies and Case Analysis

Effective learning ought to be contextual. Therefore, we will present you with real case developments in which the expert will guide you through focusing on and solving the different situations: a clear and direct way to achieve the highest degree of understanding.

Testing & Retesting

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

Classes

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

Quick Action Guides

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

10

Certificate

The Hybrid Master's Degree in MBA in Clinical Trials Management and Monitoring guarantees students, in addition to the most rigorous and up-to-date education, access to a Hybrid Master's Degree diploma issued by TECH Global University.

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

This private qualification will allow you to obtain a **Hybrid Master's Degree diploma in Management and Monitoring of Clinical Trials** endorsed by **TECH Global University**, the world's largest online university.

TECH Global University is an official European University publicly recognized by the Government of Andorra (***official bulletin***). Andorra is part of the European Higher Education Area (EHEA) since 2003. The EHEA is an initiative promoted by the European Union that aims to organize the international training framework and harmonize the higher education systems of the member countries of this space. The project promotes common values, the implementation of collaborative tools and strengthening its quality assurance mechanisms to enhance collaboration and mobility among students, researchers and academics.

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

Title: **Hybrid Master's Degree in Management and Monitoring of Clinical Trials**

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

Duration: **12 months**

Certificate: **TECH Global University**

Recognition: **60 + 4 ECTS Credits**


tech global university

Mr./Ms. _____, with identification document _____
has successfully passed and obtained the title of:

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

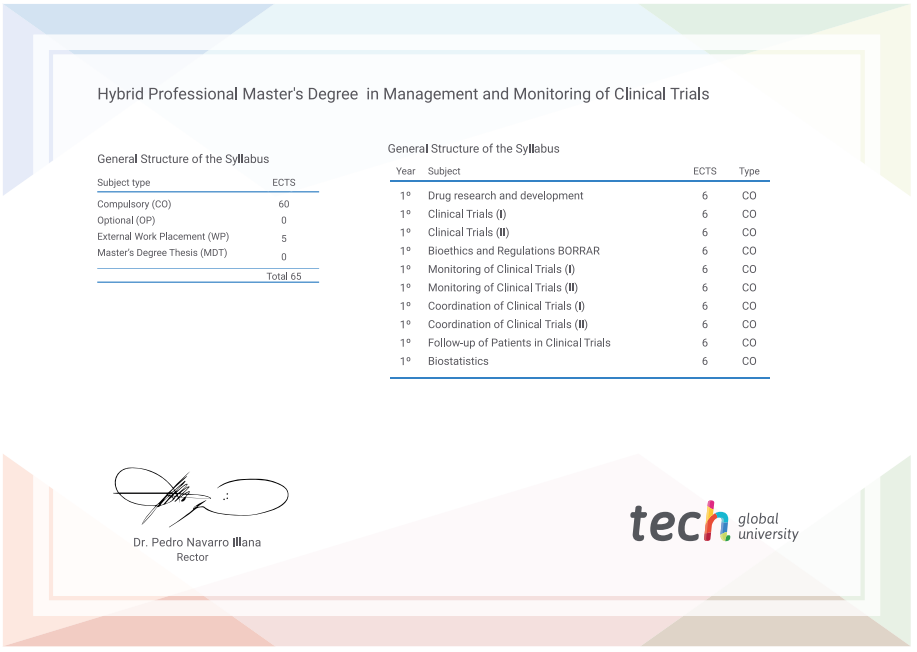
This is a private qualification of 1,920 hours of duration equivalent to 64 ECTS, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH Global University is a university officially recognized by the Government of Andorra on the 31st of January of 2024, which belongs to the European Higher Education Area (EHEA).

In Andorra la Vella, on the 28th of February of 2024

Dr. Pedro Navarro Illana
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 Management and Monitoring of Clinical Trials

General Structure of the Syllabus

Subject type	ECTS
Compulsory (CO)	60
Optional (OP)	0
External Work Placement (WP)	5
Master's Degree Thesis (MDT)	0
	Total 65

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	Bioethics and Regulations BORRAR	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	Follow-up of Patients in Clinical Trials	6	CO
1º	Biostatistics	6	CO

Dr. Pedro Navarro Illana
Rector

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

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Hybrid Master's Degree

MBA in Clinical Trials Management and Monitoring

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

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Hybrid Master's Degree

MBA in Clinical Trials Management and Monitoring

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