Master's Degree

MBA in Clinical Trials Management and Monitoring

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Master's Degree

MBA in Clinical Trials Management and Monitoring

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

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

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01

Introduction

The pharmaceutical industry is a sector in a constant process of research. The creation of new drugs to help cure new diseases or those for which there is still no cure does not stop advancing and, therefore, there is a need to create specific specialization courses with a high academic level such as the one we present on this occasion for pharmacists.

Learn about the main techniques on clinical trials thanks to this very complete specialization offered by the leading online university in Spanish: TECH”

The importance of research in the pharmaceutical field means that public and private institutions are increasingly allocating more resources to this field and, therefore, more specialists with specific knowledge in this field are needed to achieve greater advances and, therefore, greater effectiveness in the treatments prescribed for certain diseases.

For the realization of this Master's Degree, the teaching team, professionals with years of teaching and research experience, has made a careful selection of topics, useful to experienced professionals working in the field. In this way, this program specializes the health professionals in the field of clinical trials, being able to access the field of the pharmaceutical industry in the management and monitoring of clinical studies.

The program brings together the most advanced web 2.0 communication tools, which support working methods that encourage interaction among students, the exchange of information and constant and active participation, in addition to offering a theoretical and Internship Program taught by professionals with extensive experience.

Thanks to this Master's Degree, students will have the tools and skills necessary to successfully develop their professional activity in the broad environment of clinical trials, work on key competencies such as knowledge of the reality and language of healthcare, develop responsibility in the monitoring and supervision of their activities, as well as communication skills within the essential teamwork.

As it is an online Master's Degree, the students are not conditioned by fixed schedules or the need to move to another physical location, but can access the contents at any time of the day, balancing their work or personal life with their academic life.

This **MBA in Clinical Trials Management and Monitoring** contains the most complete and up-to-date scientific program on the market. The most important features include:

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

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

This MBA is the best investment you can make when selecting a refresher program to update your knowledge in Clinical Trial Management and Monitoring"

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

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

The teaching staff includes professionals from the healthcare field, who bring their work experience to this training program, as well as renowned specialists from leading companies and prestigious universities.

The multimedia content, developed with the latest educational technology, will provide the professional with situated and contextual learning, i.e., a simulated environment that will provide immersive specialization programmed to learn 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 professional will be assisted by an innovative interactive video system developed by renowned and experienced experts in the field of clinical trial management and monitoring.

02

Objectives

The MBA in Clinical Trials Management and Monitoring is aimed at facilitating the performance of the research professionals with the latest advances and most innovative treatments in the sector.

Thanks to this Master's Degree you will be able to specialize in Management and Monitoring of Clinical Trials and learn about the latest advances in the field"

General Objectives

- Establish the phases involved in the development of a new drug
- Analyze the steps prior to the development of a clinical trial (preclinical research)
- Examine how a drug is introduced into the market after the clinical trial has been conducted
- Establish the basic structure of a clinical trial
- Justify the difference between different types of clinical trials
- Compile the essential documents and procedures within a clinical trial
- Develop the clinical trial drug circuit from the point of view of the pharmacy service
- Analyze universal ethical principles
- Compile the rights and duties of the different parties involved in clinical trials
- Substantiate the concept of monitoring
- Analyze the content of a clinical research protocol and appreciate the commitment that a good compliance with it entails
- Master the skills necessary for project development and management.
- Define the monitoring process of a clinical trial, having the necessary documentation, tools and guidance for this role, taking into account the main problems that may be encountered
- Present the latest scientific advances in clinical trial monitoring tasks, with knowledge adapted to the real needs of companies in the pharmaceutical sector
- Present the wide range of tasks involved in conducting a CT and what is involved at each stage of the clinical trial
- Explain the practical aspects of conducting a CT and the role of the monitor
- Analyze the importance of the role of the trial coordinator in clinical research.
- Specify the main functions of the research team and their involvement with the patient.
- Establish the main components of a clinical trial and observational study
- Develop specialized knowledge about the variety of tasks they have to perform during the development of the study
- Establish tools and strategies to address the different problems that arise during the clinical trial, in order to obtain satisfactory results in patient monitoring
- Develop knowledge that provides a basis or opportunity for originality in the development and/or application of ideas, often in a research context
- Apply the acquired knowledge and resolution skills in the development of protocols
- Structure statistical methods and techniques
- Communicate and transmit statistical results through the preparation of different types of reports, using terminology specific to the fields of application
- Compile, identify and select sources of public biomedical information, from international agencies and scientific organizations, on the study and dynamics of populations.
- Analyze the scientific method and work on skills in the management of information sources, bibliography, protocol elaboration and other aspects considered necessary for the design, execution and critical assessment
- Demonstrate logical thinking and structured reasoning in determining the appropriate statistical technique

Specific Objectives

Module 1. Drug research and development

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

Module 2. Clinical Trials (I)

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

Module 3. Clinical Trials (II)

- Specify the different activities related to sample management (reception, dispensing, custody...) 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. 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
- Generate 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
- Justify the importance of maintaining good communication between team members involved in the development of a clinical trial

Module 5. Monitoring of Clinical Trials (II)

- Establish the basic points of a monitoring and closing visit
- Develop the monitor's 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 6. 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 7. 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 8. 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 9. 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

Module 10. Leadership, Ethics and Social Responsibility in Companies

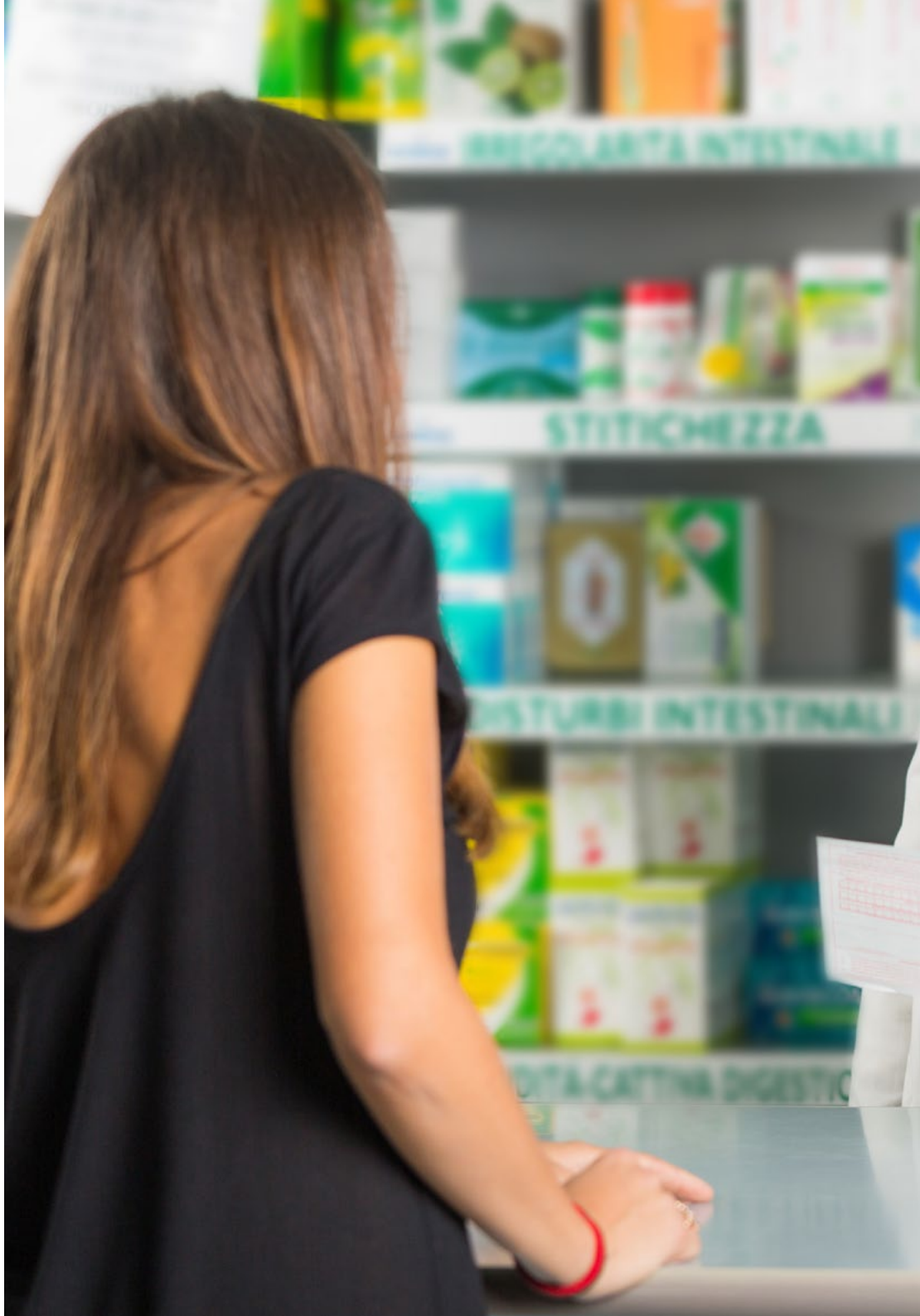
- Analyze the impact of globalization on corporate governance and corporate social responsibility
- Evaluate the importance of effective leadership in the management and success of companies
- Define cross-cultural management strategies and their relevance in diverse business environments
- Develop leadership skills and understand the current challenges faced by leaders
- Determine the principles and practices of business ethics and their application in corporate decision making
- Structure strategies for the implementation and improvement of sustainability and social responsibility in business

Module 11. People and Talent Management

- Determine the relationship between strategic direction and human resources management.
- Delve into the competencies necessary for the effective management of human resources by competencies
- Delve into the methodologies for performance evaluation and management
- Integrate innovations in talent management and their impact on employee retention and staff loyalty
- Develop strategies for motivation and development of high performance teams
- Propose effective solutions for change management and conflict resolution in organizations

Module 12. Economic and Financial Management

- Analyze the macroeconomic environment and its influence on the national and international financial system
- Define the information systems and Business Intelligence for financial decision-making
- Differentiate key financial decisions and risk management in financial management
- Evaluate strategies for financial planning and obtain business financing



Module 13. Commercial and Strategic Marketing Management

- Structure the conceptual framework and the importance of commercial management in companies
- Delve into the fundamental elements and activities of marketing and their impact on the organization
- Determine the stages of the strategic marketing planning process
- Evaluate strategies to improve corporate communication and the digital reputation of the company

Module 14. Executive Management

- Define the concept of General Management and its relevance in business management
- Evaluate the roles and responsibilities of managers in organizational culture
- Analyze the importance of operations management and quality management in the value chain
- Develop interpersonal communication and public speaking skills for the formation of spokespersons

03

Skills

After passing the evaluations of the MBA in Clinical Trials Management and Monitoring for Pharmacists, the professionals will have acquired the necessary competencies for a quality and updated practice based on the most innovative teaching methodology.

Learn about the new tools in the Management and Monitoring of Clinical Trials to offer a better care to your patients”

General Skills

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

We offer you the opportunity to get qualified in this fast-moving field"

Specific Skills

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

04

Course Management

The program's teaching staff includes leading experts in research and healthcare, who bring their work experience to this specialization. In addition, other experts of recognized prestige participate in its design and elaboration, completing the program in an interdisciplinary manner.

The leading MBA experts in Clinical Trials Management and Monitoring have come together to show you all their expertise in this field"

International Guest Director

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

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

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

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

Ms. Dove, Jennifer

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

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

International Guest Director

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

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

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

D. Gauthier, Rick

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

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

International Guest Director

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

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

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

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

Mr. Arman, Romi

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

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

International Guest Director

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

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

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

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

Mr. Arens, Manuel

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

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

International Guest Director

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

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

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

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

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

Ms. La Sala, Andrea

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

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

International Guest Director

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

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

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

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

Mr. Gram, Mick

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

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

International Guest Director

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

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

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

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

Mr. Stevenson, Scott

- Director of Digital Marketing at Warner Bros. Discovery, Burbank, United States
- Traffic Manager at Warner Bros. Entertainment.
- M.A. in Creative Writing from the University of California
- B.S. in Telecommunications from the University of Florida

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

International Guest Director

Eric Nyquist, Ph.D., is a leading **international sports professional**who has built an impressive career, noted for his **strategic leadership** and ability to drive change and **innovation** in **world-class** sports organizations.

In fact, he has held senior roles such as **Director of Communications and Impact** at **NASCAR**,based in **Florida, USA.** With many years of experience behind him at NASCAR, Dr. Nyquist has also held several leadership positions, including **Senior Vice President of Strategic Development** and **General Manager of Business Affairs,** managing more than a dozen disciplines ranging from **strategic development** to **entertainment marketing.**

Nyquist has also made a significant mark on **Chicago's top** sports franchises. As **Executive Vice President** of the **Chicago Bulls** and **Chicago White Sox** franchises, he has demonstrated his ability to drive **business** and **strategic success** in the world of **professional sports.**.

Finally, it is worth noting that he began his career in **sports** while working in **New York** as a **senior strategic analyst** for **Roger Goodell** in the **National Football League (NFL)** and, prior to that, as a **Legal Intern** with the **United States Football Federation.**

Mr. Nyquist, Eric

- Director of Communications and Impact at NASCAR, Florida, USA
- Senior Vice President of Strategic Development at NASCAR, Florida, United States
- Vice President of Strategic Planning at NASCAR
- Senior Director of Business Affairs at NASCAR
- Executive Vice President at Chicago White Sox Franchises
- Executive Vice President at Chicago Bulls Franchises
- Manager of Business Planning at the National Football League (NFL)
- Business Affairs/Legal Intern with the United States Soccer Federation
- Juris Doctor from the University of Chicago
- Master's Degree in Business Administration-MBA from the University of Chicago Booth School of Business
- B.A. in International Economics from Carleton College.

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Management

Dr. Gallego Lago, Vicente

- 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.

High School

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- Master's Degree in Biostatistics, Complutense University

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05

Structure and Content

The structure of the contents has been designed by the best professionals in research and health, with an extensive background and recognized prestige in the profession, backed by the volume of cases reviewed, studied and diagnosed, and with extensive mastery of new technologies.

This MBA in Clinical Trials Management and Monitoring contains the most complete and up-to-date scientific program on the market"

Module 1. Drug Research and Development

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

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

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

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

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

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

1.7. Uses in Special Situations
- 1.7.1. Introduction
- 1.7.2. Examples

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

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

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

Module 2. Clinical Trials (I)

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

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

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

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

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

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

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

2.8. Guidelines for the Development of a Clinical Trial Protocol
- 2.8.1. Summary
- 2.8.2. Index
- 2.8.3. General Information
- 2.8.4. Justification
- 2.8.5. Hypothesis and Objectives of the Trial
- 2.8.6. Trial Design
- 2.8.7. Selection and Withdrawal of Subjects
- 2.8.8. Treatment of Subjects
- 2.8.9. Efficacy Assessment
- 2.8.10 Safety Assessment
  - 2.8.10.1. Adverse Events
  - 2.8.10.2. Management of Adverse Events
  - 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
3.2.1.3. Centralized Preparation Unit
3.2.1.4. Facilities
3.2.1.5. Individual Protection Equipment
3.2.1.6. Closed Systems and Handling Equipment
3.2.1.7. Technical Aspects of Preparation
3.2.1.8. Cleaning Standards
3.2.1.9. Waste Treatment in the Preparation Area
3.2.1.10. Actions in Case of Spill and/or Accidental Exposure
3.2.2. Accounting/Inventory
3.2.3. Return/Destruction
3.2.4. Reports and Statistics

3.3. Involvement of the Pharmacy Service in the Realization of Clinical Trials Role of the Pharmacist
3.3.1. Visits Manager
3.3.1.1. Pre-selection Visit
3.3.1.2. Initiation Visit
3.3.1.3. Monitoring Visit
3.3.1.4. Audits and Inspections
3.3.1.5. 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. Pre-selection 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. Longterm Monitoring Visits
3.5.2. Safety Assessments
3.5.2.1. Adverse Effects Management
3.5.2.2. SAEs Management
3.5.2.3. Assigned Treatment Emergency Unblinding
3.5.3. Study Administration
3.5.3.1. Dose-Limiting Toxicities
3.5.3.2. Interrupting the Treatment
3.5.4. Quality Control and Compliance
3.5.4.1. Authorization of Subjects Protected Health Information
3.5.4.2. Retention of Study Records and Files
3.5.4.3. Data Collection Notebooks
3.5.4.4. Protocol Amendments
3.5.5. Conclusions
3.6. Approval of a Clinical Trial to the Urology Service Steps to Follow Trial Conclusion
3.6.1. Feasibility
3.6.2. Pre-selection Visit
3.6.2.1. Main Investigators Role
3.6.2.2. Logistics and Hospital Resources
3.6.3. Documentation
3.6.4. Initiation Visit
3.6.5. Source Document
3.6.5.1. Patient's Clinical History
3.6.5.2. Hospital Reports
3.6.6. Vendors
3.6.6.1. Interactive Web Response Systems (IWRS)
3.6.6.2. Electronic Case Report Form (eCRF)
3.6.6.3. Images
3.6.6.4. Suspected Unexpected Serious Adverse Reactions (SUSARs)
3.6.6.5. Accounting
3.6.7. Education
3.6.8. Delegation of Functions
3.6.9. Visit to Other Services Involved
3.6.10. Closing the Trial
3.7. General Information about Clinical Trials in Children and Adolescents
3.7.1. History of Clinical Trials in Children
3.7.2. Informed Consent
3.8. Clinical Trials in Adolescents
3.8.1. Adolescents Clinical Trials Practical Features
3.8.2. New Approaches to Adolescent Trials

3.9. Clinical Trials in Children
  3.9.1. Specific Physiological Characteristics of the Child
  3.9. 2. Children Clinical Trials
3.10. Clinical Trials in Neonatal
  3.10.1. Specific Physiological Characteristics the Neonatal
  3.10.2. Neonatal Clinical Trials

Module 4. Monitoring of Clinical Trials (I)

4.1. Promoter I
  4.1.1. General Aspects
  4.1.2. Promoter Responsibilities
4.2. Promoter II
  4.2.1. Project Management
  4.2.2. Non-commercial Research
4.3. Protocol
  4.3.1. Definition and Content
  4.3.2. Protocol Compliance
4.4. Monitoring
  4.4.1. Introduction
  4.4.2. Definition
  4.4.3. Monitoring Objectives
  4.4.4. Types of Monitoring: Traditional and Risk-Based
4.5. Clinical Trial Monitor I
  4.5.1. Who can be a Monitor?
  4.5.2. CRO: Clinical Research Organization
  4.5.3. Monitoring Plan
4.6. Clinical Monitor II
  4.6.1. Monitors Responsibilities
  4.6.2. Verification of Source Documents Source Documents Verification (SDV)
  4.6.3. Monitors Report and Monitoring Letter
4.7. Selection Visit
  4.7.1. Researcher Selection
  4.7.2. Aspects to take into Account
  4.7.3. Suitability of Facilities
  4.7.4. Visit to other Hospital Services
  4.7.4. Deficiencies in Study Facilities and Staffing
4.8. Start Up in a Clinical Research Center
  4.8.1. Definition and Functionality
  4.8.2. Essential Documents at the Beginning of the Trial
4.9. Initiation Visit
  4.9.1. Objective
  4.9.2. Preparing the Initiation Visit
  4.9.3. Investigators File
  4.9.4. Investigator Meeting
4.10. Hospital Pharmacy Initiation Visit
  4.10.1. Objective
  4.10.2. Investigational Drug Management
  4.10.3. Controlling Temperature
  4.10.4. General Deviation Procedure

Module 5. Monitoring of Clinical Trials (II)

5.1. Follow-Up Visit
  5.1.1. Preparation
    5.1.1.1. Letter Confirming the Visit
    5.1.1.2. Preparation

5.1.2. Center Development
5.1.2.1. Documentation Review
5.1.2.2. SAEs
5.1.2.3. Inclusion and Exclusion Criteria
5.1.2.4. Collate
5.1.3. Research Team Training
5.1.3.1. Monitoring
5.1.3.1.1. Monitoring Report Preparation
5.1.3.1.2. Issues Tracking
5.1.3.1.3. Team Support
5.1.3.1.4. Monitoring Letter
5.1.3.2. Temperature
5.1.3.2.1. Adequate Medication
5.1.3.2.2. Reception
5.1.3.2.3. Expiration
5.1.3.2.4. Dispensing
5.1.3.2.5. Setting Up
5.1.3.2.6. Return
5.1.3.2.7. Storage
5.1.3.2.8. Documentation
5.1.3.3. Samples
5.1.3.3.1. Local and Central
5.1.3.3.2. Types
5.1.3.3.3. Temperature Registration
5.1.3.3.4. Calibration/Maintenance Certificate
5.1.3.4. Meeting with the Research Team
5.1.3.4.1. Signature of Pending Documentation
5.1.3.4.2. Discussion of Findings
5.1.3.4.3. Re-Training
5.1.3.4.4. Corrective Actions
5.1.3.5. Review of ISF (Investigator Site File)
5.1.3.5.1. Clinical Investigations (CIs) and Protocols
5.1.3.5.2. New Approvals from the Ethics Committee and the AEMPS
5.1.3.5.3. LOGs
5.1.3.5.4. Site Visit Letter
5.1.3.5.5. New Documentation
5.1.3.6. Suspected Unexpected Serious Adverse Reactions (SUSARs)
5.1.3.6.1. Concept
5.1.3.6.2. Principal Investigator Review
5.1.3.7. Electronic Notebook
5.2. Close-Out Visit
5.2.1. Definition
5.2.2. Reasons for Close-Out Visits
5.2.2.1. Completion of the Clinical Trial
5.2.2.2. Not Complying with Protocol
5.2.2.3. Not Complying with Good Clinical Practices
5.2.2.4. At the Investigators Request
5.2.2.5. Low Recruitment
5.2.3. Procedures and Responsibilities
5.2.3.1. Before the Close-Out Visit
5.2.3.2. During the Close-Out Visit
5.2.3.3. After the Close-Out Visit
5.2.4. Pharmacy Close-Out Visit
5.2.5. Final Report
5.2.6. Conclusions
5.3. Queries Management, Database Slicing
5.3.1. Definition
5.3.2. Queries Rules
5.3.3. How are Queries Generated?
5.3.3.1. Automatically
5.3.3.2. By the Monitor
5.3.3.3. By an External Reviewer

5.3.4. When are Queries Generated?
5.3.4.1. After a Monitoring Visit
5.3.4.2. Close to Closing a Database
5.3.5. Query Status
5.3.5.1. Open
5.3.5.2. Pending Revision
5.3.5.3. Closed
5.3.6. Database Slicing
5.3.5.1. Most Frequent Database Slicing Errors
5.3.7. Conclusions
5.4. AE Management and SAE Notification
5.4.1. Definitions
5.4.1.1. Adverse Events Adverse Event (AE)
5.4.1.2. Adverse Reactions (AR)
5.4.1.3. Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)
5.4.1.4. Suspected Unexpected Serious Adverse Reaction (SUSAR) (SUSAR)
5.4.2. Data to be Collected by the Researcher
5.4.3. Collection and Assessment of the Safety Data Obtained in the Clinical Trial
5.4.3.1. Description
5.4.3.2. Dates
5.4.3.3. Unraveling
5.4.3.4. Intensity
5.4.3.5. Actions Taken
5.4.3.6. Causality Relationship
5.4.3.7. Basic Questions
5.4.3.7.1. Who Notifies, What is Notified, Who is Notified, How are they Notified, When are they Notified?

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

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

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

5.7. Protocol Deviations
- 5.7.1. Criteria
  - 5.7.1.1. Non-Compliance with Inclusion Criteria
  - 5.7.1.2. Compliance with Exclusion Criteria
- 5.7.2. International Classification of Functioning (ICF) Deficiencies
  - 5.7.2.1. Correct Signatures on Documents (CI, LOG)
  - 5.7.2.2. Correct Dates
  - 5.7.2.3. Correct Documentation
  - 5.7.2.4. Correct Storage
  - 5.7.2.5. Correct Version
- 5.7.3. Out-Of-Window Visits
- 5.7.4. Poor or Wrong Documentation
- 5.7.5. The 5 Rights Medication Administration
  - 5.7.5.1. Right Patient
  - 5.7.5.2. Right Drug
  - 5.7.5.3. Right Time
  - 5.7.5.4. Right Dose
  - 5.7.5.5. Right Route
- 5.7.6. Missing Samples and Parameters
  - 5.7.5.1. Missing Samples
  - 5.7.5.2. Parameter Not Performed
  - 5.7.5.3. Sample Not Sent On Time
  - 5.7.5.4. Time of Sample Collection
  - 5.7.5.5. Request for Kits Out of Time
- 5.7.7. Information Privacy
  - 5.7.7.1. Information Security
  - 5.7.7.2. Reporting Security
  - 5.7.7.3. Photo Security
- 5.7.8. Temperature Deviations
  - 5.7.8.1. Register
  - 5.7.8.2. Inform.
  - 5.7.8.3. Act
- 5.7.9. Open Blinding at the Wrong Time
- 5.7.10. PI Availability
  - 5.7.10.1. Not Updated in Interactive Voice Response Services (IVRS)
  - 5.7.10.2. Not Sent on Time
  - 5.7.10.3. Not Registered on Time
  - 5.7.10.4. Broken Stock
- 5.7.11. Forbidden Medication
- 5.7.12. Key and Non-Key

5.8. Source and Essential Documents
- 5.8.1. Features
- 5.8.2. Source Documents Location
- 5.8.3. Source Document Access
- 5.8.4. Source Document Types
- 5.8.5. How to Correct a Source Document
- 5.8.6. Source Document Retention Time
- 5.8.7. Main Components of the Medical History
- 5.8.8. Investigator's Brochure (IB)

5.9. Monitoring Plan
- 5.9.1. Visits
- 5.9.2. Frequency (F)
- 5.9.3. Organization
- 5.9.4. Confirmation
- 5.9.5. Site Issues Categorization
- 5.9.6. Communication with Researchers
- 5.9.7. Research Team Training
- 5.9.8. Trial Master File
- 5.9.9. Reference Documents
- 5.9.10. Electronic Notebooks Remote Review
- 5.9.11. Data Privacy
- 5.9.12. Center Management Activities

5.10. Data Collection Notebooks
- 5.10.1. Concept and History
- 5.10.2. Timeline Compliance
- 5.10.3. Data Validation
- 5.10.4. Management of Data Inconsistencies or Queries
- 5.10.5. Data Exports
- 5.10.6. Security and Roles
- 5.10.7. Traceability and Logs
- 5.10.8. Report Generation
- 5.10.9. Notifications and Alerts
- 5.10.10. Electronic Notebook vs. Paper Notebook

Module 6. Coordination of Clinical Trials (I)

6.1. The Researcher's File – General Aspects
- 6.6.1. What is the Researcher's File? What type of Documentation Should It Contain and Why? How Long Should the Information be Stored?
- 6.6.2. Contract
  - 6.6.2.1. Original Copies
  - 6.6.2.2. Amendments
- 6.6.3. Ethical Committees
  - 6.6.3.1. Approvals
  - 6.6.3.2. Amendments
- 6.6.4. Regulatory Authorities
  - 6.6.4.1. Approvals
  - 6.6.4.2. Modifications
  - 6.6.4.3. Monitoring and Final Reports
- 6.6.5. Civil Liability Insurance

6.2. Documentation Associated with the Research Team
- 6.2.1. CV
- 6.2.2. Good Clinical Practice Certificate
- 6.2.3. Specific Education Certificates
- 6.2.4. Signed Statement of the Investigator, "Financial Disclosure"
- 6.2.5. Task Delegation

6.3. Study Protocol and Monitoring
- 6.3.1. Protocol Versions, Summary and Pocket Guides
- 6.3.2. Protocol
- 6.3.3. Protocol Amendments
- 6.3.4. Protocol Signature Form

6.4. Patient Related Material
- 6.4.1. Patient Information Form and Informed Consent Form (Copies and Specimens for Signature)
- 6.4.2. Modifications to the Consent (Copies and Specimens for Signature)
- 6.4.3. Study Participation Cards
- 6.4.4. Information for Primary Care Physician
- 6.4.5. Questionnaires

6.5. Patient Forms, Monitoring Visits
- 6.5.1. Patient (Screening) Form
- 6.5.2. Patient Recruitment and Identification Form
- 6.5.3. Visit Logs and Reports Form

6.6. Data Collection Notebooks (DCNs)
- 6.6.1. Types
- 6.6.2. Guide or Manual for Data Entry in the DCN
- 6.6.3. Copy of DCN

6.7. Investigator's Brochure (Studies with Medical Devices) or Fact Sheet (Clinical Trials with Medication)
- 6.7.1. Investigators Brochure (IB)
- 6.7.2. Technical Data Sheets of the Drugs Under Study (If Marketed)
- 6.7.3. Instructions for the Control of Specific Parameters (e.g. Temperature)
- 6.7.4. Instructions for Return of Medication or Medical Devices

6.8. Material Related to Laboratory and Specific Procedures
- 6.8.1. Central Laboratories and Sample Shipping Documents
- 6.8.2. Local Laboratory: Qualification Certificates and Ranks
- 6.8.3. Instructions for Acquiring and/or Processing Medical Images
- 6.8.4. Sample and Material Shipment

6.9. Security/Safety
- 6.9.1. Adverse Events and Serious Adverse Events
- 6.9.2. Notification Instructions
- 6.9.3. Relevant Security Correspondence

6.10. Others
- 6.10.1. Contact Information
- 6.10.2. Note to File
- 6.10.3. Correspondence with the Promoter
- 6.10.4. Acknowledgements of Receipt
- 6.10.5. Newsletter

Module 7. Coordination of Clinical Trials (II)

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

7.2. Trial Coordinator
- 7.2.1. Responsibilities
  - 7.2.1.1. Primary Responsibilities
  - 7.2.1.2. Secondary Responsibilities
- 7.2.2. Capabilities and Competencies
  - 7.2.2.1. Academic Background
  - 7.2.2.2. Skills
- 7.2.3. Clinical Trials vs. Observational Study
  - 7.2.3.1. Types of Clinical Trials
  - 7.2.3.2. Types of Observational Studies

7.3. Protocol
- 7.3.1. Primary and Secondary Objectives
  - 7.3.1.1. What Are They and Who Defines Them?
  - 7.3.1.2. Importance During the Course of the Clinical Trial
- 7.3.2. Inclusion and Exclusion Criteria
  - 7.3.2.1. Inclusion Criteria
  - 7.3.2.2. Exclusion Criteria
  - 7.3.2.3. Example
- 7.3.3. Flowchart
  - 7.3.3.1. Document and Explanation
- 7.3.4. Concomitant Medication and Prohibited Medication
  - 7.3.4.1. Concomitant Drug
  - 7.3.4.2. Forbidden Medication
  - 7.3.4.3. Washout Periods

7.4. Documentation Required to Initiate Clinical Trial
- 7.4.1. Curriculum of the Research Team
  - 7.4.1.1. Basic Notions of a Research Curriculum
  - 7.4.1.2. Good Clinical Practice Example
- 7.4.2. Good Clinical Practice
  - 7.4.2.1. Origin of Good Clinical Practices
  - 7.4.2.2. How to Get Certified?
  - 7.4.2.3. Expiration
- 7.4.3. Suitability of the Research Team
  - 7.4.3.1. Who Signs the Document?
  - 7.4.3.2. Presentation to Ethics Committee
- 7.4.4. Suitability of Facilities
  - 7.4.4.1. Who Signs the Document?
  - 7.4.4.2. Ethical Committee Presentation
- 7.4.5. Calibration Certificates
  - 7.4.5.1. Calibration
  - 7.4.5.2. Calibration Equipment
  - 7.4.5.3. Valid Certifications
  - 7.4.5.4. Expiration
- 7.4.6. Other Training
  - 7.4.6.1. Necessary Certifications According Protocol

7.5. Main Functions Trial Coordinator
- 7.5.1. Documentation Preparation
  - 7.5.1.1. Documentation Requested for Approval of the Study at the Center
- 7.5.2. Investigator Meeting
  - 7.5.2.1. Importance
  - 7.5.2.2. Attendees
- 7.5.3. Initiation Visit
  - 7.5.3.1. Duties of the Coordinator
  - 7.5.3.2. Functions of the Principal Investigator and Subinvestigators
  - 7.5.3.3. Promoter
  - 7.5.3.4. Monitor
- 7.5.4. Monitoring Visit
  - 7.5.4.1. Preparation After a Monitoring Visit
  - 7.5.4.2. Functions During the Monitoring Visit
- 7.5.5. End-Of-Study Visit
  - 7.5.5.1. Storage of the Researchers File

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

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

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

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

7.10. Biological Treatments
- 7.10.1. Coordination of Clinical Trials with Biologicals
  - 7.10.1.1. Biological Treatments
  - 7.10.1.2. Types of Treatment
- 7.10.2. Types of Studies
  - 7.10.2.1. Biological Criteria Placebo
  - 7.10.2.2. Biological Criteria Biological Criteria
- 7.10.3. Biological Management
  - 7.10.3.1. Administration.
  - 7.10.3.2. Traceability
- 7.10.4. Rheumatic Diseases
  - 7.10.4.1. Rheumatoid Arthritis
  - 7.10.4.2. Psoriatic Arthritis
  - 7.10.4.3. Lupus
  - 7.10.4.4. Scleroderma

Module 8. Follow-up of Patients in Clinical Trials

8.1. Patient Care in Outpatient Clinics
- 8.1.1. Visits in the Protocol
  - 8.1.1.1. Visits and Procedures
  - 8.1.1.2. Window of Realization of the Different Visits
  - 8.1.1.3. Database Considerations

8.2. Materials Used in the Different Study Visits
- 8.2.1. Questionnaires
- 8.2.2. Drug Adherence Cards
- 8.2.3. Symptom Cards
- 8.2.4. Study Card
- 8.2.5. Electronic Devices
- 8.2.6. Suicide Risk Scales
- 8.2.7. Material for the Displacement of Patients
- 8.2.8. Others

8.3. Strategies for Patient Retention:
- 8.3.1. Possible Causes for Abandonment of a Clinical Trial
- 8.3.2. Strategies and Solutions to the Possible Causes of Abandonment
- 8.3.3. Long-Term Monitoring of Patients Leaving the Study Prematurely

8.4. Loss of Patient Follow-Up:
- 8.4.1. Definition of Loss of Monitoring
- 8.4.2. Causes of Loss of Monitoring
- 8.4.3. Resumption of Monitoring
  - 8.4.3.1. Re-Inclusion Back into the Protocol

8.5. Adherence to Pharmacological Treatment under Study
- 8.5.1. Calculation of Adherence to Pharmacological Treatment
- 8.5.2. Risk Factors for Therapeutic Non-Compliance
- 8.5.3. Strategies to Strengthen Adherence to Treatment
- 8.5.4. Treatment Dropout
- 8.5.5. Study Drug Interactions

8.6. Follow-Up of Adverse Reactions, and Symptom Management in the Study Medication Intake.
- 8.6.1. Study Medication
  - 8.6.1.1. Different Drug Presentations
  - 8.6.1.2. Procedure and Preparation of Study Medication
- 8.6.2. Drug-Related Adverse Reactions
- 8.6.3. Non-Drug Related Adverse Reactions
- 8.6.4. Adverse Reaction Treatment

8.7. Monitoring of Patient Attendance at Study Visits
- 8.7.1. Visit Calculator
- 8.7.2. Study Visits Control
- 8.7.3. Tools for Compliance and Visitor Control

8.8. Difficulties in Patient Monitoring Within a Clinical Trial
- 8.8.1. Problems Related to Adverse Patient Events
- 8.8.2. Problems Related to the Patients Work Situation
- 8.8.3. Problems Related to the Patients Residence
- 8.8.4. Problems Related to the Patients Legal Status
- 8.8.5. Solutions and their Treatments

8.9. Moniotoring of Patients in Treatment with Psychopharmaceuticals

8.10. Monitoring of Patients During Hospitalization

Module 9. Biostatistics

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

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

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

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

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

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

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

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

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

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

Module 10. Leadership, Ethics and Social Responsibility in Companies

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

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

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

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

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

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

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

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

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

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

Module 11. People and Talent Management

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

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

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

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

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

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

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

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

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

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

Module 12. Economic and Financial Management

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

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

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

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

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

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

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

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

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

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

Module 13. Commercial and Strategic Marketing Management

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

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

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

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

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

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

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

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

13.9. Corporate Communication
- 13.9.1 Concept
- 13.9.2 The Importance of Communication in the Organization
- 13.9.3 Type of Communication in the Organization
- 13.9.4 Functions of Communication in the Organization
- 13.9.5 Elements of Communication
- 13.9.6 Communication Problems
- 13.9.7 Communication Scenarios

13.10. Digital Communication and Reputation
- 13.10.1. Online Reputation
- 13.10.2. How to Measure Digital Reputation?
- 13.10.3. Online Reputation Tools
- 13.10.4. Online Reputation Report
- 13.10.5. Online Branding

Module 14. Executive Management

14.1. General Management
- 14.1.1. The Concept of General Management
- 14.1.2. The Role of the CEO
- 14.1.3. The CEO and their Responsibilities
- 14.1.4. Transforming the Work of Management

14.2. Manager Functions: Organizational Culture and Approaches
- 14.2.1. Manager Functions: Organizational Culture and Approaches

14.3. Operations Management
- 14.3.1. The Importance of Management
- 14.3.2. Value Chain
- 14.3.3. Quality Management

14.4. Public Speaking and Spokesperson Education
- 14.4.1. Interpersonal Communication
- 14.4.2. Communication Skills and Influence
- 14.4.3. Communication Barriers

14.5. Personal and Organizational Communications Tools
- 14.5.1. Interpersonal Communication
- 14.5.2. Interpersonal Communication Tools
- 14.5.3. Communication in the Organization
- 14.5.4. Tools in the Organization

14.6. Communication in Crisis Situations
- 14.6.1. Crisis
- 14.6.2. Phases of the Crisis
- 14.6.3. Messages: Contents and Moments

14.7. Preparation of a Crisis Plan
- 14.7.1. Analysis of Possible Problems
- 14.7.2. Planning
- 14.7.3. Adequacy of Personnel

14.8. Emotional Intelligence
- 14.8.1. Emotional Intelligence and Communication
- 14.8.2. Assertiveness, Empathy, and Active Listening
- 14.8.3. Self-Esteem and Emotional Communication

14.9. Personal Branding
- 14.9.1. Strategies for Personal Brand Development
- 14.9.2. Personal Branding Laws
- 14.9.3. Tools for Creating Personal Brands

14.10. Leadership and Team Management
- 14.10.1. Leadership and Leadership Styles
- 14.10.2. Leader Capabilities and Challenges
- 14.10.3. Managing Change Processes
- 14.10.4. Managing Multicultural Teams

This will provide key education to advance your career"

06

Methodology

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

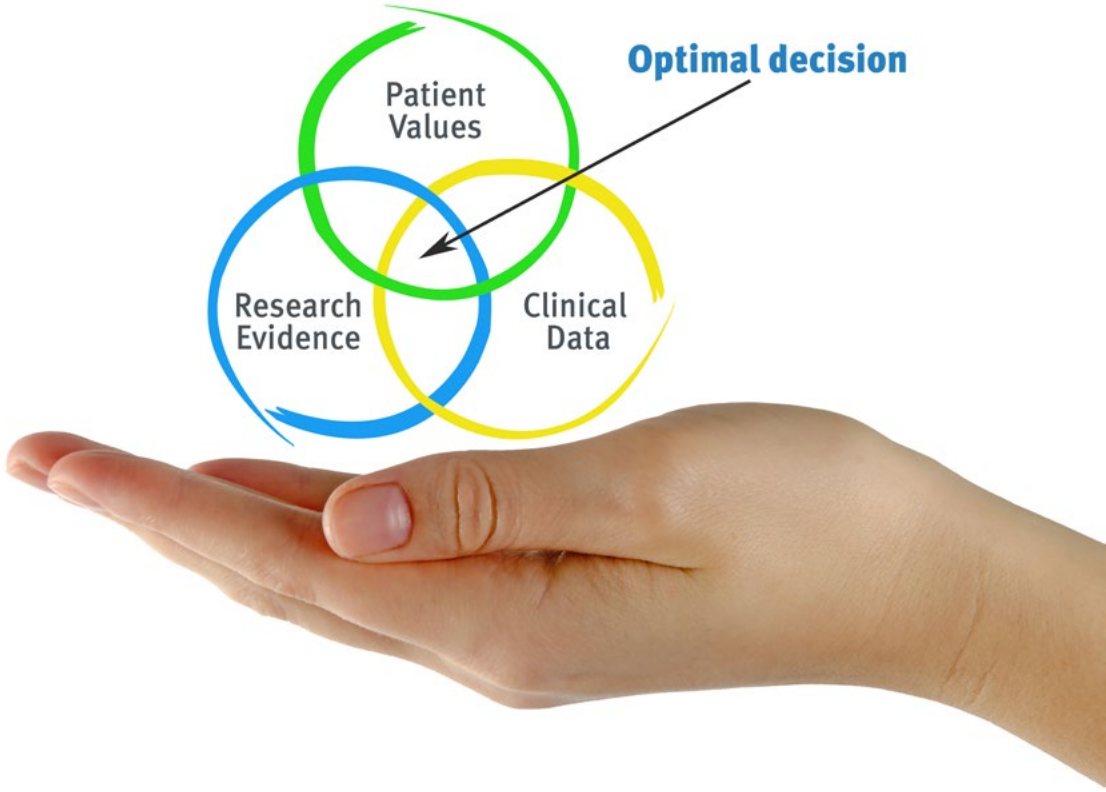
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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

At TECH 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:

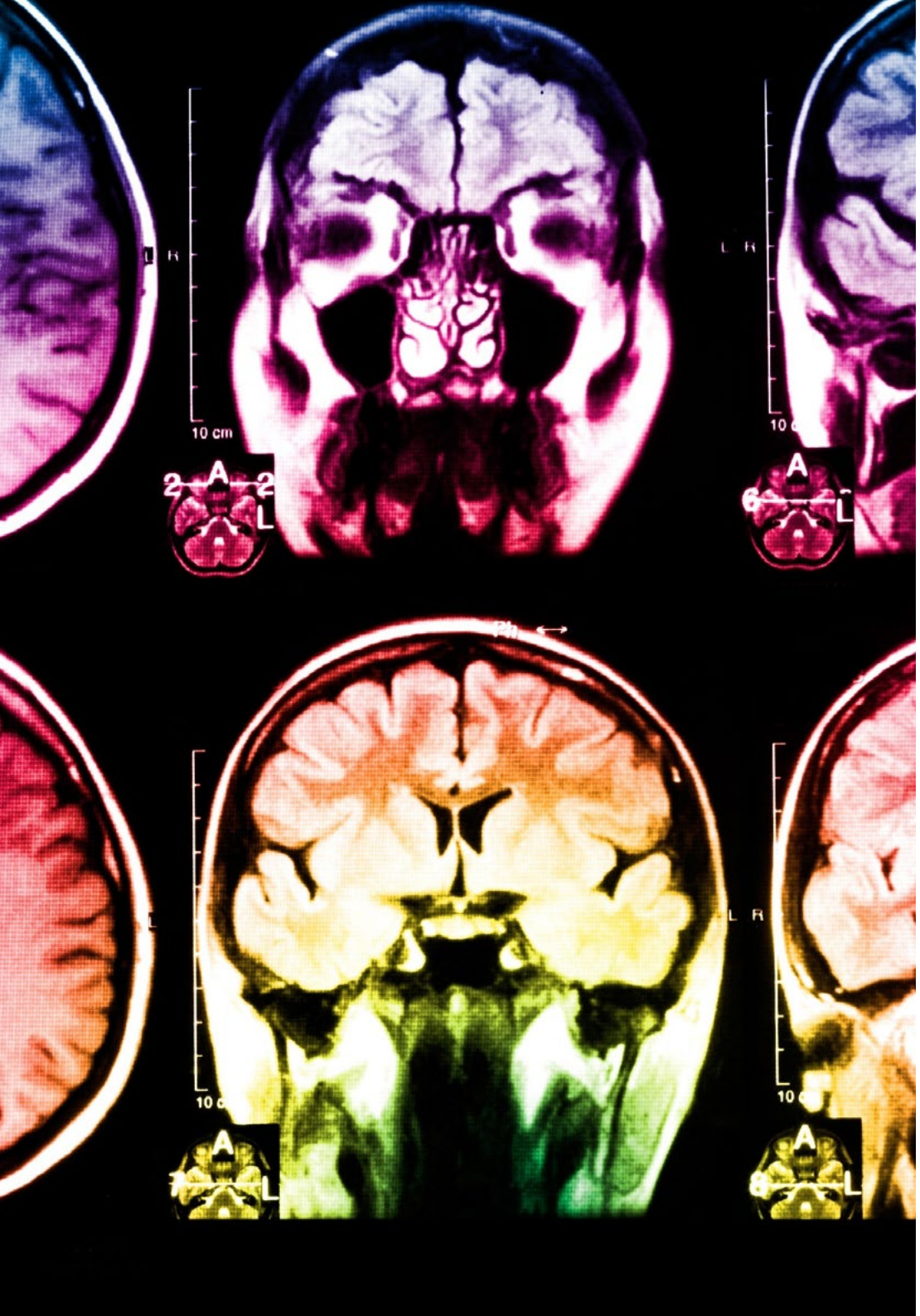
1. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts 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.

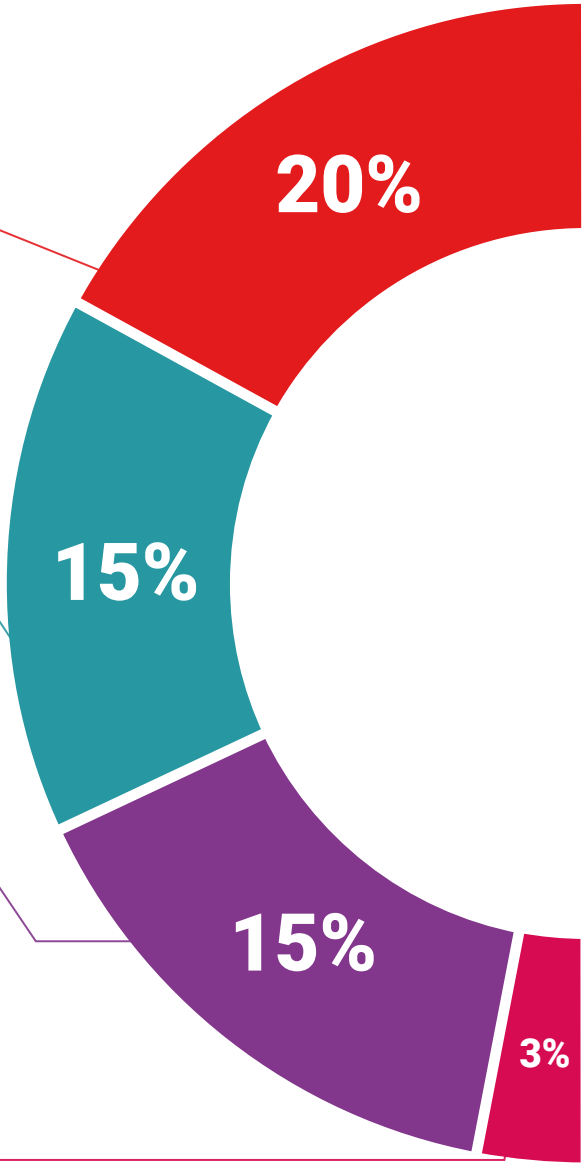
Interactive Summaries

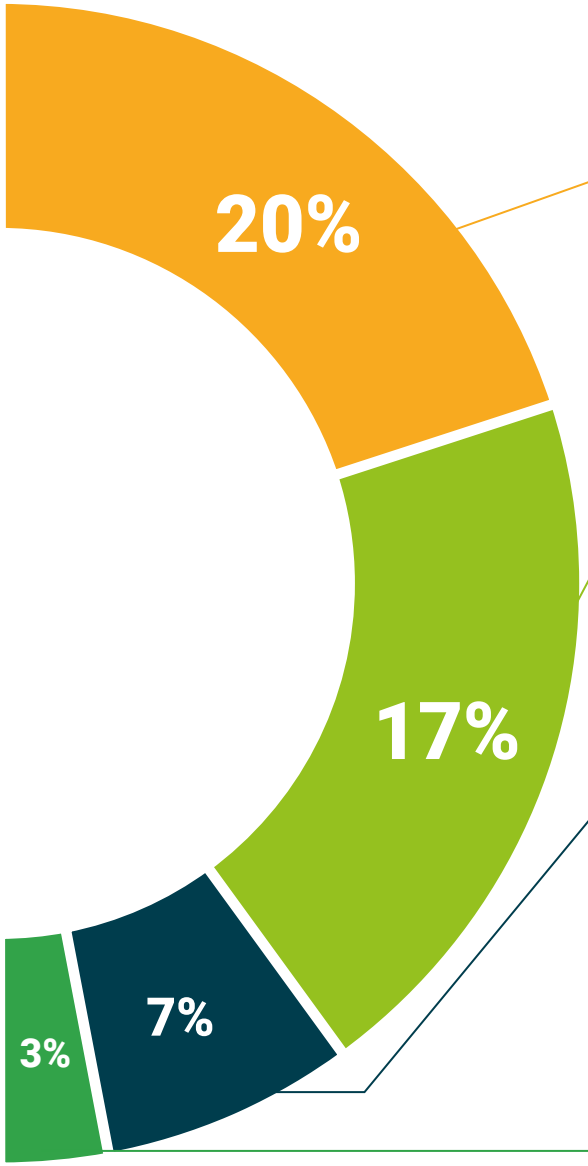
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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.

07

Certificate

The MBA in Clinical Trials Management and Monitoring guarantees, in addition to the most rigorous and up-to-date education, access to a Master's Degree 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 Master's Degree diploma **MBA in Clinical Trials Management and Monitoring** 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: **Master's Degree MBA in Clinical Trials Management and Monitoring**

Modality: **online**

Duration: **12 months**

Accreditation: **90 ECTS**

tech global university

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

Master's Degree MBA in Clinical Trials Management and Monitoring

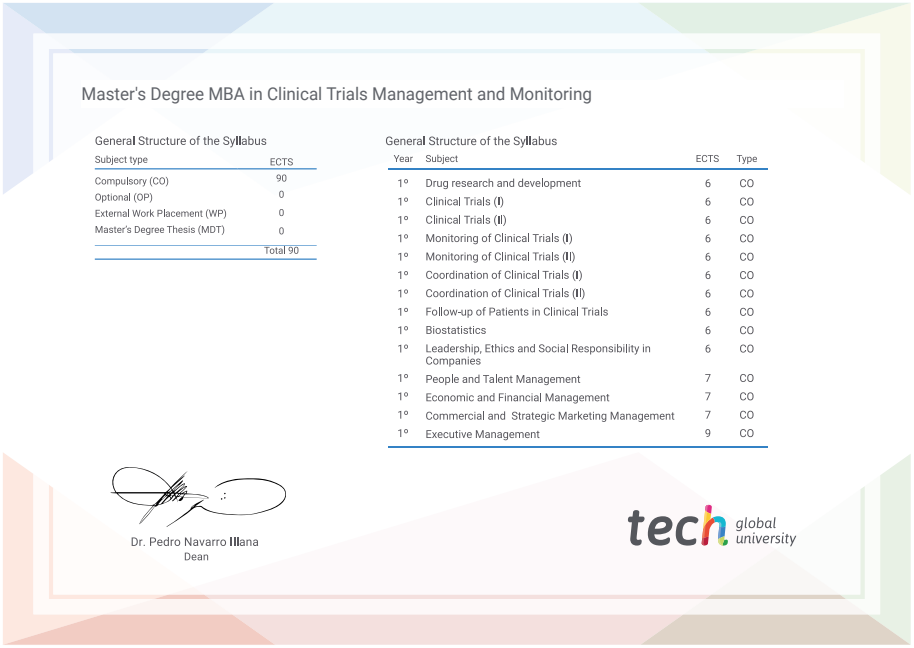
This is a private qualification of 2,700 hours of duration equivalent to 90 ECTS, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

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



Master's Degree MBA in Clinical Trials Management and Monitoring

General Structure of the Syllabus

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

General Structure of the Syllabus

Year	Subject	ECTS	Type
1º	Drug research and development	6	CO
1º	Clinical Trials (I)	6	CO
1º	Clinical Trials (II)	6	CO
1º	Monitoring of Clinical Trials (I)	6	CO
1º	Monitoring of Clinical Trials (II)	6	CO
1º	Coordination of Clinical Trials (I)	6	CO
1º	Coordination of Clinical Trials (II)	6	CO
1º	Follow-up of Patients in Clinical Trials	6	CO
1º	Biostatistics	6	CO
1º	Leadership, Ethics and Social Responsibility in Companies	6	CO
1º	People and Talent Management	7	CO
1º	Economic and Financial Management	7	CO
1º	Commercial and Strategic Marketing Management	7	CO
1º	Executive Management	9	CO

Dr. Pedro Navarro Illana
Dean

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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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Master's Degree
MBA in Clinical Trials Management and Monitoring

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

Master's Degree

MBA in Clinical Trials Management and Monitoring

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