

Internship Program

MBA in Management and Monitoring of Clinical Trials



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Monitoring of Clinical Trials

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01 Introduction

Degenerative diseases, cancer or the generation of new vaccines have focused scientific research and the creation of new medicines in recent decades. However, the great push in investment that came after the Coronavirus pandemic has highlighted the role of the pharmaceutical professional and investment in research. A reality that has led, in turn, specialists to seek to update their knowledge on the direction and development of Clinical Trials. This is why this 100% practical program was born, where the professional will spend 3 weeks in a specialized reference center together with professionals with experience in this field. A space where you can stay up to date with the latest news on the latest techniques and methods used in Clinical Trials.



This Internship Program will update your daily practice in the area of Clinical Trial Monitoring, for 3 weeks in a reference health center"





In recent years, the increase in infectious diseases and the pandemic caused by COVID 19 have led public and private institutions to adopt new formulas to enhance the I+D+i and retain talent in the field of research. This scenario opens up an excellent opportunity for pharmaceutical professionals who wish to update and expand their scientific-technical knowledge about the Management and Monitoring of Clinical Trials.

Faced with this reality, TECH has created this Internship Program, which provides pharmaceutical professionals with a stay in a prestigious research center. In this space, the specialist will obtain an update on the techniques, methods and protocols used in the coordination and conducting Clinical Trials. A period where you will expand your skills together with a team of professionals with extensive experience in this field.

Thus, over 3 weeks the student will become part of a team of top-level professionals, with whom they will actively work. In this way, you will be able to update not only the most effective strategies, but you will also be able to implement the most assertive communication skills and leadership skills into your praxis that will allow you the best practice in Management and Monitoring of Clinical Trials, in a scenario real and cutting edge.



This program provides you with a complete update of your knowledge in the field of clinical trial monitoring”

02

Why Study an Internship Program?

For the Pharmacist, training and constant updating is essential, since it consolidates all their skills and knowledge with the new technical resources that scientific and technological advances make available to them. Thanks to the 100% practical activity that TECH offers in this program, you will be able to catch up on the phases involved in the development of a new medicine and check the previous steps. , Develop specialized knowledge about the variety of tasks they have to perform during the development of the study. All this and more in a real investigative space, with exemplary and innovative cases that will allow you to broaden your perspective regarding this matter. You will do it with the accompaniment of an assigned tutor, for 3 weeks where you will see first-hand the latest scientific findings in the area.



Check in situ the progress regarding the development of Clinical Trials and update your knowledge regarding the direction and monitoring of this process”

1. Updating from the latest technology available

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

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

The large team of professionals that will accompany the specialist throughout the entire practical period is a first-class endorsement and a guarantee of unprecedented updating. With a specifically designated tutor, the student will be able to see real Clinical Trials in a cutting-edge environment, which will allow them to incorporate new knowledge regarding the Direction and Monitoring of these studies.

3. Entering first-class Scientific environments

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



4. Putting the acquired knowledge into daily practice from the very first moment

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

5. Expanding the Boundaries of Knowledge

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



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

03

Objectives

TECH has designed this Internship Program to be able to offer professionals a practical and recent vision of the advances that are being produced in the monitoring of clinical trials. A stay where the specialist will be able to verify, together with experts from reference centers, how the teams in charge of carrying out research in said area are promoted and directed.



General Objectives

- ♦ Master the latest techniques, modern scientific postulates and application of cutting-edge technologies in the Management and Monitoring of Clinical Trials
- ♦ Know the specific approach to new drug developments
- ♦ Incorporate the most effective methods, approaches and investigative analyzes into daily work, endorsed by a team of prestigious experts in the pharmaceutical sector





Specific Objectives

- ♦ 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
 - ♦ 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
 - ♦ Specify the different activities related to sample management (reception, dispensing, custody...) in which the Pharmacy team is involved



This Internship Program will allow you to be up to date on the technical and administrative processes necessary in drug research in humans”

04 Educational Plan

The Internship Program MBA in Management and Monitoring of Clinical Trials made up of a stay in a reference research center. Moreover, for 3 weeks, the professional will remain, from Monday to Friday, working 8 consecutive hours alongside specialists with extensive experience in clinical trials.

A period where the professional will be able to update their knowledge and expand their skills in managing research teams. In addition, it will enhance its technical capabilities on the methods and protocols currently used in clinical trial monitoring processes.

In this training proposal, completely practical in nature, the activities are aimed at developing and perfecting the skills necessary for the provision of Clinical Research, conditions that require a high level of qualification, and are oriented towards specific training for the exercise of the activity, in a safe environment and high professional performance.

It is, without a doubt, an excellent opportunity to obtain a direct and practical vision in a space where research and scientific rigor go hand in hand. In this way, TECH offers a new way of understanding and integrating innovative processes through an experience that promotes the improvement of professional skills and competencies.

The practical teaching will be carried out with the active participation of the student performing the activities and procedures of each area of competence (learning to learn and learning to do), with the accompaniment and guidance of teachers and other training partners that facilitate teamwork and multidisciplinary integration as transversal competencies for medical practice (learning to be and learning to relate).

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



Receive specialized education in an institution that can offer you all these possibilities, with an innovative academic program and a human team that will help you develop your full potential"



Module	Practical Activity
Research and Development of Medicines	Participate in the Develop from all phases of a clinical trial
	Identify and know how to use the different drugs that can be used in clinical trials
	Collect clinical trial data for further analysis
	Publish research results in different formats
Clinical Trials Coordination	Provide support in the presentation of documentation for the implementation clinical trial underway
	Identify all the documents to be contained in the researchers file and managing in the communication of the results of clinical trials through the most appropriate means in each case
	Manage and provide support in the global monitoring process
	Establish research protocols for Clinical Trials
Bioethics and regulations in development of Clinical Trials	Carry out the whole process of clinical trials following the current legislation on the matter
	Participate in the Develop from a safety surveillance plan for marketed drugs
	Recognize and comply with the rules governing Clinical Trials
	Monitor patients participating in research projects
Follow-up of Patients in Clinical Trials	Manage monitoring visits and closure of the clinical trial
	Collaborate in the Assess from the treatments and possible adverse effects caused by some drugs
	Participate in the Develop Clinical from Trials with the collaboration of the hospital pharmacist
	Ensure the safety of participants in Clinical Trials

05

Where Can I Do the Internship Program?


TECH carefully selects the research center, where the professional will spend their stay, in order to be able to offer a quality knowledge update. This is possible thanks to the team of experienced specialists, who will guide the graduate, as well as the facilities and equipment that will be at their disposal during the 3 weeks of Internship Program.



Take your Internship Program in a prestigious research center alongside professionals with extensive experience in clinical trials”



The student will be able to do this program at the following centers:

Pharmacy

IdiPAZ

Country	City
Spain	Madrid

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

La Paz University Hospital Research Institute

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



Pharmacy


Histocell Regenerative Medicine

Country	City
Spain	Vizcaya

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

Histocell Regenerative Medicine are experts in Production of Cellular Therapy and Biological Drugs

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

Pharmacy

Hospital Italiano La Plata

Country	City
Argentina	Buenos Aires

Address: Av. 51 N° 1725 e/ 29 y 30 La Plata, Buenos Aires

Nonprofit Community Center
 specialized clinical assistance

Related internship programs:
 - Advanced Emergency Medicine
 - Gynecologic Oncology

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General Conditions

Civil Liability Insurance

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

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

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



General Conditions of the Internship Program

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

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

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

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

4. CERTIFICATION: Professionals who pass the Internship Program will receive a certificate accrediting their stay at the center.

5. EMPLOYMENT RELATIONSHIP: The Internship Program shall not constitute an employment relationship of any kind.

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

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

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

07 Certificate

This **Internship Program in MBA in Management and Monitoring of Clinical Trials** contains the most complete and up-to-date program on the professional and educational field.

After the student has passed the evaluations, they will receive their corresponding TECH Internship Program issued by TECH Technological University via tracked delivery.

The certificate issued by TECH will reflect the grade obtained in the test.

Title: **Internship Program in MBA in Management and Monitoring of Clinical Trials**

Duration: **3 weeks**

Course Modality: **Monday to Friday, 8-hour consecutive shifts**

Total Hours: **120 h. of professional practice**



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