Academic Journal of Health Sciences & Research

Iris Publishers

Short Communication

Introducing Start-ups to Clinical Trials – Understanding the role of CROs

Sami Ben Abdallah*

Clinical Operations Project Manager, BluePharm, Paris, France

Corresponding author: Sami Ben Abdallah, Clinical Operations Project Manager, Blue Pharm, Paris, France

Received Date: July 09, 2024

Published Date: August 02, 2024

Introduction

Moving on to a human clinical trial is a decisive step in the development of any drug or medical device. If you are an innovative start-up (focusing on the discovery of a new therapeutic route, targeted immunotherapy, DMD via AI...), it is important to understand the role of the CRO (Contract Research Organization) who is in charge of clinical studies.

The CRO is involved in 7 stages

Preparing the Protocol

- Define the objectives of the clinical study.
- Design the protocol detailing inclusion and exclusion criteria, doses to be tested, safety measures, etc.

Obtaining regulatory approvals

- Submit the protocol to the relevant regulatory authorities to obtain ethical and legal approval to conduct the clinical trial.

Recruiting clinical investigation sites

- Identify and select qualified medical centers and investigators to conduct the clinical trial.

Managing participants

- Recruit study participants according to inclusion criteria.
- Obtain participants' informed consent to take part in the clinical trial.

Data Management

- Collect, monitor and manage clinical data accurately and in compliance with regulations.

Quality control

- Ensure compliance with Good Clinical Practice (GCP) and applicable regulations throughout the clinical trial.

Data analysis and reporting

- Analyze the data collected and write a detailed report on the results of the clinical trial.

In addition, the CRO:

- Provides the expertise needed to design the clinical protocol efficiently and in compliance with regulations.
- Has a network of clinical trial sites and qualified investigators, facilitating recruitment of study participants.
- Ensures data quality through rigorous monitoring processes and compliance with high quality standards.
- Also enables the efficient management of resources in terms of time and costs, which is fundamental for innovative companies with limited resources
- What is the link between start-ups and CROs?

In the process of developing a drug or medical device, start-

ups and CROs work closely together to bring clinical trials to a successful conclusion. Effective collaboration with a CRO can speed up the clinical trial process while ensuring quality and regulatory compliance.

Collaboration between the startup and the CRO

Identifying and selecting the CRO

The start-up seeks out and selects a CRO that has the necessary expertise in the specific therapeutic area and matches its needs in terms of size, geographical scope and capabilities.

Setting objectives and budget

The start-up and the CRO work together to define the clinical study objectives, the success criteria and the trial budget.

Clinical protocol design

In collaboration with the start-up, the CRO helps design the clinical protocol, taking into account regulatory requirements, best clinical practices and the specific objectives of the study.

Project management

The CRO is responsible for the day-to-day management of the clinical trial, including trial site selection, participant recruitment, data collection and management, and monitoring of regulatory compliance.

Communication and reporting

Throughout the clinical trial, the start-up and the CRO maintain close communication to ensure total transparency and a rapid resolution of any problems. The CRO provides regular progress reports to the start-up.

Data analysis and final report

Once the clinical trial is complete, the CRO analyses the data collected and, in collaboration with the start-up, draws up a final report detailing the results of the study.

In this collaboration, the startup remains the driving force behind innovation, providing scientific expertise and strategic vision, while the CRO brings its operational experience, mastery of regulatory requirements and technical capabilities to bear on clinical trials. Together, they form a solid team that works in synergy to advance the development of new therapies or innovative medical devices.

What are the Challenges, step by step

For Drug development

Preclinical evaluation: the first steps in the development

Preclinical studies mark the first steps in drug development. They provide preliminary data on the behavior of a molecule in cultured cells and in living animal organisms. During preclinical evaluation, the molecule of interest is tested on three different species, including rodents. The data studied are pharmacological, pharmacokinetic and toxicological: mechanism of action, rate of diffusion in the organism, distribution of the molecule in tissues, active dose, mode of transformation and elimination by the organism, fate of the compound and environmental impact, toxicity... All this data is required to compile the marketing application file. In addition, this stage enables us to estimate the dose to be administered to humans, based on the no-toxic-effect dose in animals converted into a human equivalent.

Since the 1980s, major efforts have been made to limit the use of animals and improve their treatment conditions. Between 1984 and 1999, the number of animals used for drug development fell by half and has remained stable since. New cell-culture models and computer programs for simulating therapeutic effects on specific targets will enable us to further reduce the use of animals in the years to come, or to dispense with certain invasive practices. Nonetheless, animal experimentation on whole, living organisms remains essential before moving on to humans.

Clinical evaluation in humans: safety and effectiveness

The clinical evaluation of a drug candidate marks the start of its testing in humans. The aim is to assess the drug's safety and effectiveness in healthy or sick volunteers. The drug may reach the market if its benefit/risk balance is positive, i.e. if its health benefits outweigh its potential drawbacks.

For Medical Devices (MD)

Development, from project inception to final product

At what stage does a clinical trial take place in the development of a MD? When it comes to the clinical evaluation of a MD, there are fewer prerequisites than for drugs. There are no standardized regulatory early phases, and CE marking is imposed on manufacturers. CE marking reflects the MD's compliance with the general product performance and safety requirements set out in European regulations 2017/745 (MDR) and 2017/746 (IVDR), respectively applicable from May 2021 and May 2022. Directives 93/42/EEC and 90/385/EEC have been repealed. The general requirements set the objectives to achieve to ensure the MD is designed in such a way that its use does not compromise either the clinical condition of patients, or the safety and health of patients and users.

For all MDs, except those in class 1, affixing the mark is subject to obtaining a CE certificate issued by a notified body (NB) authorized by the competent authorities. In France for example, the competent authority is the ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé). There may be several notified bodies per country. The notified body assesses the conformity of the procedure followed by the manufacturer. Depending in particular on the class of medical device, the assessment is carried out by examining the design file supplied by the manufacturer, or by testing the product itself. The assessment also covers the production system set up by the manufacturer, by means of on-site audits. The sum of these elements ensures that the medical device complies with general requirements in line with technical standards (electrical safety, sterility, biological compatibility), and integrates the evaluation of clinical data.

The medical device must achieve the performances assigned to it by the manufacturer. Any risks must be acceptable in relation to the benefits to the patient. Once on the market, the MD is placed under the responsibility of the manufacturer who markets and monitors it. Audits are carried out periodically at the manufacturer's premises by the notified body (for instance GMED and AFNOR in France). CE marking is subject to periodic renewal. In France, the ANSM is involved in market surveillance and control, and may be called upon to take action on MDs, up to and including withdrawal from the market.