HOW TO MANAGE

Global clinical trials

WITH AN EFFECTIVE IMPLEMENTATION

AICROS

How to manage global clinical trials with an effective implementation

Introduction

There are many reasons to conduct a global clinical trial. With all multicentered clinical trials, there are requirements such as a coordinating figure to take responsibility for the management of all data for the final analysis.

When we set up a multicentered clinical trial (and more so when the study is global), we should consider **expert support.**

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The decision to conduct a global study will depend on the sponsor's development goals. For example if the study is being conducted to include the information on the marketing authorization dossier, and the intention is to reach more than one country, a multinational study is warranted.

For the pharma and biotech industries, the aim is for the product to reach **as many markets and patients as possible** to access the benefit of the medication/ product, but also to maximize the financial return to the investors.

The advantages and disadvantages of international clinical trials

Before deciding whether to conduct an international multicenter study over a local clinical trial, **the main advantages of international clinical trials should be considered:**

Recruitment. More countries mean greater access to patients. In the case of orphan diseases, global studies can reduce recruitment time.

Qualified team. More sites across various countries allows access to a lot more investigators eager to participate in clinical studies.

Growing countries. Conducting clinical trials in less developed countries reduces the overall cost of the study. These studies also make it possible to provide the drug to a population that otherwise may not have no access to a particular treatment.

Improve quality of data by understanding the variability in drug response.

Ethnic and cultural differences. For some products there might some differences between races that may need to be considered when conducting global clinical trials.

Varied information. When managing global clinical trials, the information obtained would be more diverse, which should increase the reliability of the data.

We should however also consider **the challenges conducting a global clinical trial:**

- A **global clinical trial infrastructure** is required to manage an international multicentered trial.
- There are **language and cultural differences** that must be overcome.
- **Quality assurance and harmonization** is required.
- The **regulatory framework is different in every country,** and we need to adapt our activity to accommodate these differences.
- There may be **longer timelines in the startup process** due to site selection, regulatory approvals and contract negotiation with sites. Such delays may be offset by the reduced recruitment period required.

Main factors to focus on your clinical studies

When conducting a **global study** there are some factors to focus on to ensure the successful execution of these studies.

Project Team and Management

We recommend a full-service solution to conduct a clinical trial which is committed to transparency and provides professional project management specifically trained to manage and implement global studies with clear roles and responsibilities defined.

For every country involved it will be necessary to consider if local adaptations, validations and translations are required.

Study Design

The study and the protocol should take cultural factors, variability between countries, the incidence of the disease and the local standard of care or the access to the medicine after the study has finished into account.

Logistics

Implementing and conducting global clinical trials involving many regions is a challenge that could be managed by planning and clear communication between the team involved in the clinical study. The best approach is for all people working on a project be well aware of the study specific procedures.

Countries, Sites and Investigators Involved

Some **factors that should be taken into account** when selecting the countries beside the adherence of the country to the ICH-GCP standards, are: disease incidence in the country, sites desire to participate in the study, patient recruitment rate, quality adherence in the country, timelines and costs. For every country involved it will be necessary to consider if **local adaptations, validations and translations are required.**

Sites and investigators: A site feasibility is a great tool for a high-level assessment between sites and countries. However, as sites in each country vary in their performance and ability, site selection should not only be finalised with a feasibility questionnaire. The on-site site qualification will help assess each site's ability and capacity. Local management of this activity and previous knowledge of the site's capacity is required. **Engaging with a CRO with specific local knowledge and expertise will assist in the success of this process.**

Involving a CRO from the beginning of the project will lead you to successful execution of the international trial

Trial Tracking

Data collected from all different sources involved in a clinical trial can be a challenge. Using a **centralized control system** integrating new technologies makes the process faster and more cost effective. By using **global electronic data capture** combined with **cloud computing** in the data collection, the collaboration between sponsors, vendors and other parties involved in a global clinical study will be optimized, as will the analyses of the data and, as a result, the cost of the study.

Local 'Knowhow'

Information in global clinical studies should be standardized as much as possible across all regions. Nevertheless, there are always **regulatory challenges in each country** to be addressed by an outsourced company with broad experience in the field. The focus will always be patient protection, transparency and quality of data.

Quality Assurance Program

International compliance with safety and regulatory standards by adherence to international standards as well as audit according to the ICH-GCP and sponsors' requirements.

Steps to success on your global clinical trial

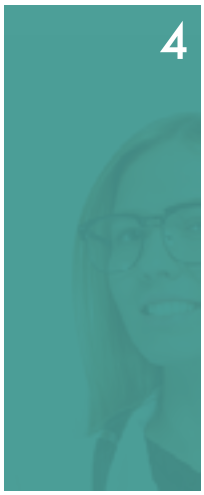
When preparing for the challenge of conducting a **global clinical trial or medical device study,** there are steps that will help to ensure the success:

Rely on an experienced CRO with global experience and local knowledge. Involving a CRO from the beginning of the project will lead you to successful execution of the international trial. The main qualities that a CRO should have for global clinical studies, are:

- A CRO should **facilitate the sponsor's work** by successfully managing the study, from the study design to the write up of the Clinical Study Report.
- Adopting an **integrated technology** to collate all sources of data.
- One of the key successes of a clinical trial are **timelines**, which can be shortened by local knowledge during the regulatory submission and during the site contract negotiation.
- **Good rapport** with sites and investigators enables the study to run smoothly and therefore more efficiently.

Test the water. Performing a feasibility study first to know the sites willing to participate in the study and the investigators expected recruitment rate. This information will help when selecting the countries as well as the disease incidence, the quality adherence, timelines and costs.

Design the study hand in hand with the CRO. Communication throughout the whole study is very important to detect any issue early or to avoid them before they even exist.



Local adaptation of the study for every country or region.

- **Compliance with global standards** such as the International Conference on Harmonization (ICH), the Good Clinical Practices (GCP) and the declaration of Helsinki.
- Include **ethnicity and cultural factors** when designing and planning a global clinical trial, otherwise it may affect the safety of the study.
- **Training** for health providers, investigators and support personnel.

Ethics is another key aspect when considering the development of a global clinical trial. Concerns have been raised whether the pharma and biotech industry is globalizing their studies to reduce risks and safety issues when involving countries where the regulation is **less restrictive,** or if the less developed countries are benefiting from this globalization of clinical trials when patients from these countries will not have access outside a clinical trial, or if the only intention while conducting global studies is to reduce costs.

There are often many opinions raised when ethical considerations are discussed. As previously discussed, multinational clinical trials involve different countries with varying degrees of development , safety regulation is restrictive in most countries to ensure the clinical trials are conducted under **ethical parameters to ensure the wellbeing of the patients,** and the main reason to conduct global clinical trials to reach as many areas and markets as possible rather than to reduce costs.

These considerations should be reviewed and being transparent with our intentions when globalizing studies is the best strategy to avoid suspicion and conspiracy allegations.

If the decision to conduct a global clinical trial is made, we should acknowledge that we have taken a challenging decision, but we should also be sure to **employ a collaborative approach using outsourcing services with global experience and local knowledge,** that can support us on our journey to achieve a **successful outcome.**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