HOW YOU CAN CONDUCT A SUCCESSFUL

CLINICAL TRIAL

EBOOK

Are you considering launching a clinical trial? Successful clinical trials hinge on their ability to plan for and adapt to unexpected challenges The response to unforeseen issues allows the trial to move forward. Effective risk management prevents the problems from influencing a clinical trial's successful setup and implementation. Let's take a closer look at considerations you should keep in mind as you navigate the complexities of clinical trials.

FACTORS TO CONSIDER FOR YOUR STUDY

Planning

In the age of international, global services and complex clinical trials, coordination and planning are key for targeting success. You have several stakeholders such as third-party vendors, the sponsor, and the Clinical Research Organization (CRO). It is also imperative to identify the best investigative sites and all other ad-hoc activities related to the trial itself, such as the selection of National Country Investigators (NCI) as applicable or the Data and Safety Monitoring Board (DSMB).

Effective project management ensures coordination is moving seamlessly. A streamlined approach also helps prevent future risks, while still being prepared for issues to occur.

Challenges And Conflicts

During a clinical trial, your study team will likely face many challenges and conflicts.

The interested parties (e.g., third-party vendors) investigative sites, CRO, sub-CROs, and sponsors will work together to identify the best solutions to meet the needs of the clinical trial, including mitigations. Transparency and complete coordination are necessary for all interested parties to work together to tackle challenges and conflicts in the timeliest and financially effective way.

The ICH GCP E6 (R2) recommends a risk-based approach to quality management that should be completed at the beginning of each clinical trial and throughout the study to help ensure that all parties work together to achieve the desired objective.

This includes the following key steps:

1 Critical Processes and Data Identification

It is necessary to establish the priorities of the clinical trial. Since you can't focus on everything, it is key to prioritize critical processes and data (e.g. Endpoints).

Failure to protect critical data or processes can jeopardize human subject protection or reliability of trial results.

2 Risk Assessment

There is more than one approach. The outcome of the risk evaluation should be recorded, communicated, and then validated at appropriate levels of the organization.

3 Risk Control

For each risk identified, an appropriate mitigation strategy (e.g., enhancing monitoring for important data such as inclusion/ exclusion or primary endpoints) should be implemented, or a determination made that the risk can be accepted or eliminated (e.g., by modifying the protocol).

If the risk is accepted, there should always be a scientific rationale for why the risks are acceptable.

You must remember that the goal is not to eliminate all risks, but to control the most significant ones.

4 Risk Communication

Once risks and actions have been determined, it is crucial to communicate those actions to the relevant stakeholders at the system and trial levels.

The purpose of communication is to assist the relevant stakeholders in understanding the risks, the basis on which decisions are made, and why particular actions are required.

5 Risk Review

You and the organization should evaluate whether actions are taken to address risks achieve the desired outcome as specified by ICH GCP. This step examines whether the identified risk was controlled appropriately and its result.

6 Risk Control

In accordance with the guidelines, the sponsor should describe the quality management approach for the trial, the implemented risk adaptations, summarize important deviations from the predefined quality tolerance limits, and remedial actions taken in the clinical study report. Make sure to add the conclusion and why this is critical if your goal is to set up a successful trial.

It is imperative to be proactive (rather than reactive) in your approach and not ignore potential issues. The quality risk management methodology is not only an integral part of an effective quality management system. It can be applied to both the system and the trial levels to mitigate risks for not being successful. ICH GCP asks for the protection of rights, safety, the wellbeing of study subjects, and the integrity of study data.

Study Considerations and Strategy

Site selection will allow you to assess the site's capabilities and forecast a plan for patient enrollment. This is a time-consuming process but worth it if you plan long-term success.

Various stakeholders are engaged in that process, from the Clinical Research Associate (CRA), Legal or Site Contract Managers to the Regulatory team. The process should be focused on working together toward site selection to site activation and the grail of the First Patient In (FPI). Each site may have a different experience with the disease, processes, regulatory or ethics committee requirements, and specific documents or requirements as a limiting factor. Hence, local knowledge and expertise are key.

The final decision to move on with a site selection requires a clear long-term strategy and understanding. Begin with the end, what do we expect from a sponsor or CRO perspectives. Site relationship, Key Opinion Leader (KOL), but also quality and site availability i.e., site staff responsiveness during Data Base Lock.

Several criteria must be considered, not only the expected enrolment committed by the site.

These are questions usually raised at the set-up of a clinical trial and assessed during the Pre- Study Visit (PSV). The information in-house will help you identify the appropriate process for the future. Specifically, it can help identify the perfect sites as a key for planning your future success in the clinical trial. This is important in your trial setup because those sites will be enrolling the patients you need.

It is necessary to remember that locating the right sites or countries are key and may depend of the global strategy (marketing, regulatory requirements, etc). Engaging the site staff and enrolling patients with high retention is even better.

APPROACHES FOR YOUR CLINICAL TRIAL SUCCESS

Once you have the appropriate sites and they start to enroll patients, your next goal should be maintaining patient retention. It's important to remember you do what you do in clinical research and how you can be passionate about contributing to improving patients' lives. Efforts for retention mean that emphasis is being placed on keeping the patient at the center of the clinical trial.

Many third-party companies are experts in retention efforts and provide support for developing a strategy and improving retention using specific tools. They can also provide insight from patient's standpoint about the visit schedule, their willingness to embrace e-consent or home-nursing. Together, this may contribute to increase patient's enrolment and retention. Of course, you can also develop some of them in-house.

So, the message would be to make it personal. Try to connect with patients in a way that says that they matter. Patient advocacy groups may be a strong asset on this matter. This is not a five-digit number you check on your Electronic Data Capture (EDC). These are real people with real outcomes that can impact their lives.

Retention Solutions

You should strive to make patient life easier and smoother while participating in a clinical trial. Being successful could also be from a patient perspective. There are now different technologies that can be used, such as the mobile app and its SMS reminder program for patient visits or medication, which can be customized.

Patient Centricity

Patient-centric research has its roots in the patient advocacy movement, where individual patients would fight for better protections, considerations, and treatment by drug companies. It's important to realize that patients are no longer recipients of healthcare; they are active participants. Clinical trials must be geared toward that concept.

It is best described as putting the patient at the heart of every part of the clinical research process. This includes co-design of the trial, patient selection, choosing the location, influence over the monitoring and evaluation process, drug pricing, and regular, impactful consultation and feedback throughout. Each study trial is different. Hence, patient's expectations and requirements will differ accordingly. Indeed, patients may be either healthy for a Ph1 or in an advance metastatic disease in a Ph3b.

Sustainability Considerations

There is no doubt that sustainability has become one of the most important challenges of our time. The purpose of clinical research is about improving patients' health or better treating them. The World Economic Forum Global Risk Report states that for the first time in the survey's 10-year outlook, the top five global risks in terms of likelihood are all environmental.

Some important questions to consider:

Finding cures for cancer won't matter if environmental issues shake the foundation of our societies.

Global disasters threaten global population security. "Green" studies may serve as an asset for patients and our planet. Ensuring that we do our part to care for the environment is a critical point in designing clinical trials.

- How can you contribute from a clinical research perspective?
- Can you aim for carbon neutrality in clinical research?
- How do you sustainably deliver projects?

For clinical research, global supply chains are severely disrupted through floods, hurricanes, and crop destruction. Besides, supply chains will be critical pathways as 80% of companies' emissions are produced here.

Societies are feeling the impacts of global warming and environmental degradation. Many solutions are available, and today the topic is about being considerate of our planet while running a clinical trial.

WHO WE ARE

From a high level overview, conducting your own clinical trial is incredibly complex with several challenges along the way. There are still many other items to consider outside of the above-mentioned insights. However, streamlining the process with an experienced project management team that you trust can make a noticeable difference.

Zanteris provides Project Management services for the successful planning and execution of clinical trials in various therapeutic settings. Our project managers offer expertise in areas such as Oncology, Onco-Immunology, Immunology, and Cardiology.

Our modern experience provides us with a clear understanding of managing global and/or complex clinical, which is essential to achieving reliable clinical trial results.

We believe that you know your study better than anybody else, and that the work you do has an opportunity to make a positive impact on people's lives. That is why we offer consulting solutions to support you while initiating a clinical trial, but also Project Management expertise to support you in achieving your enrollment expectations and outcomes. This is accomplished by utilizing a model that is dynamic, flexible, and transparent to meet the unique needs of your study.

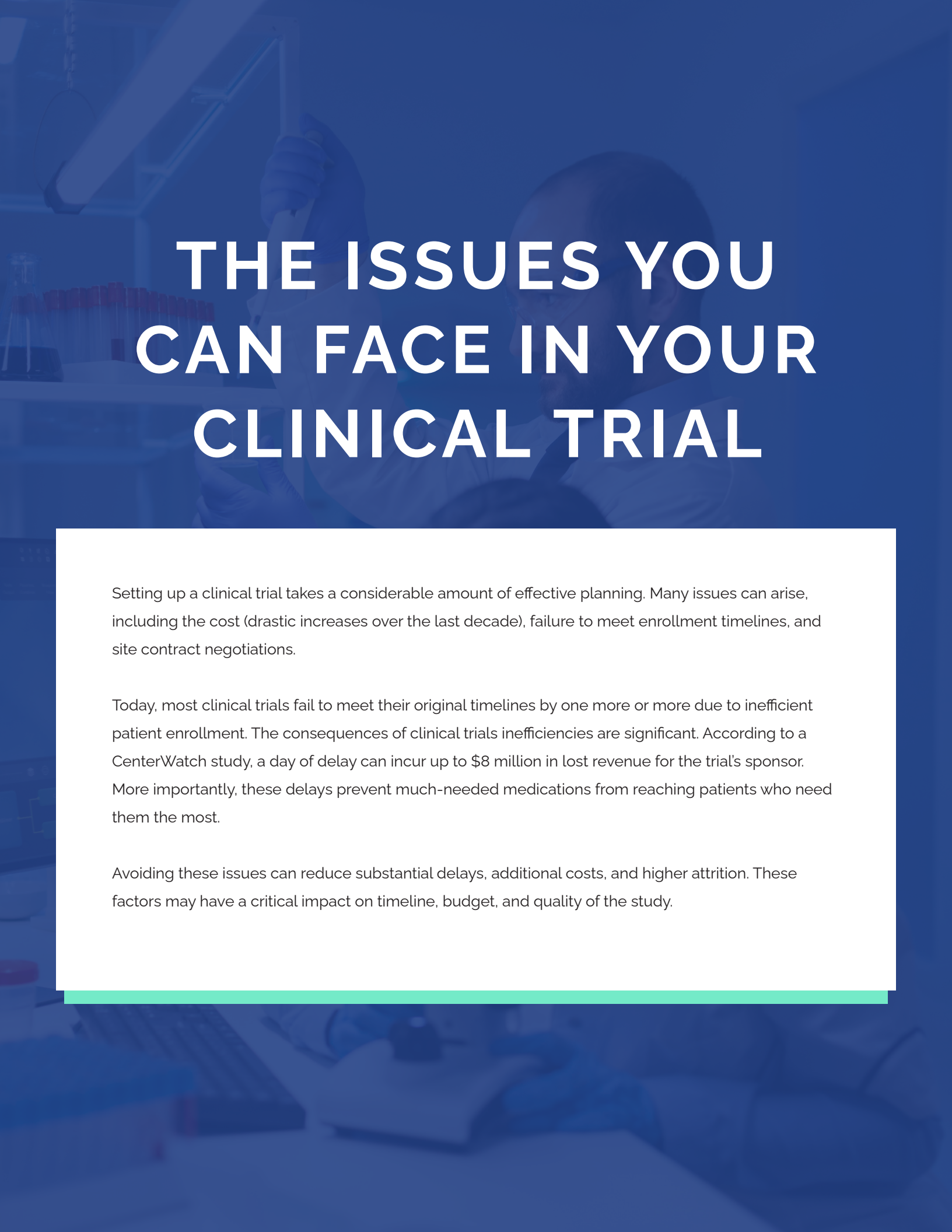
WHAT WE DO

Our model is a compilation of the most successful and groundbreaking management techniques observed through our experience in managing successful clinical trials. We are committed to helping our customers deliver quality data across a broad range of medical conditions. Our specialized team strives for study optimization and risk management throughout the entire clinical trial process; from FPI to market authorization.

Introduction

FPI is one of the most challenging aspects of initiating a clinical trial. It is no surprise that clinical trials are costly, and a significant portion of the money is lost due to the lengthy drug development timelines.

When it comes to open enrollment, it's important to note that 80% of clinical trials fail because they couldn't meet the required enrollment objectives. An additional 30% of Ph3 is terminated prematurely due to enrollment difficulties. With enrollment challenges in mind, the number one priority is identifying enrollment issues as early as possible and implementing a solution quickly and effectively. Planning and proactivity are keys for making your study a success.



THE ISSUES YOU CAN FACE IN YOUR CLINICAL TRIAL

Setting up a clinical trial takes a considerable amount of effective planning. Many issues can arise, including the cost (drastic increases over the last decade), failure to meet enrollment timelines, and site contract negotiations.

Today, most clinical trials fail to meet their original timelines by one more or more due to inefficient patient enrollment. The consequences of clinical trials inefficiencies are significant. According to a CenterWatch study, a day of delay can incur up to $8 million in lost revenue for the trial's sponsor. More importantly, these delays prevent much-needed medications from reaching patients who need them the most.

Avoiding these issues can reduce substantial delays, additional costs, and higher attrition. These factors may have a critical impact on timeline, budget, and quality of the study.

CONCLUSION

The strategies and considerations mentioned here are the three core pillars we believe helps Zanteris effectively manage clinical trials:

Integrity:

Doing the right things with strong moral principles, even when things are not going as planned.

Respect:

Mutual respect allows for better communication and allows people to rise to the occasion and expectations that people have for them. Teams work more efficiently if respect is established early.

Communication:

Communication is transferring information from one place, person, or group to another. Every communication involves (at least) one sender, a message, and a recipient. It's important to communicate so that people understand the message and intent.

We are committed to providing you with consulting and Project Management services to assist with the execution and completion of successful clinical trials. Individual expertise is valuable, but clear and concise communication across diverse teams is the cornerstone of success. Zanteris is here ensure that proper project management and implementation lead to successful clinical trials.