Top 6 Challenges in Clinical Trial Management

Clinical trial management is complex due to the inclusion of multiple factors that need to be met by any team. Even more concerning is that these factors “behave” rather unpredictable, thus influencing the processes involved in the clinical research. The negative effect is the prolonged time-span and the delayed market introduction of new drug formulas.

As a result, pharma companies seek new ways of reducing the “time-to-market” phenomenon, generally be improving the clinical trial management. They highlight the importance of accelerating the processes, shorten the time of the complete study, and making additional cost-savings as a result.

But which are the challenges that lead to the prolonged clinical studies that might not only lie in the ineffective clinical trial management? Here are our observations:

1. Approvals by the government

Obtaining governmental approvals is the most often named hindrance in initiating the trial. Regulations often set difficulties in the implementation of the trial, but they provide safety and efficacy.

2. Site Selection

This is a multiple facet issue, because it not only includes the search of suitable site for the trial, but it might also expand beside the national level and reach the international market. It also features important points like management of the selected sites, poor quality of the work at the sites, data entry issues and not meeting the deadlines.

3. Clinical trial management

The clinical trial management of the project is ineffective, when the PM has not been supplied with the appropriate tools. These include specific software systems (like CTMS), that will make their planning more systematic and will line out, which criteria and steps of the project are met, and which need to be further finished out. The limited availability of tools for planning and documentation of the visits is also a major disadvantage, especially when investigators require specific number after every report period.

4. Management of performance

Vital for the clinical trial management is the transparency over the project and its performance. The factor here include: the importance of the current status in the course of the project, the cost control at any given time, project risks, adverse events or factors, not enough study participants at given location, and eventually exceeding the budgeted costs.

5. Time management

Time management is among the greatest challenges of the Clinical Research Organizations (CRO). The complexity it is multiplied by the number of multinational studies, project with hundreds of sites, and lack of synchronicity. The role of the CROs as a service provider demands to be able to meet deadlines in order to complete the billing processes.

6. Data management

Reporting, management of data and documents is beyond disputes complex. However, it applies only to large and sophisticated studies. Its intricacy lies in the various data formats and document types that are used in one study. Different regulation requirements regarding the data are often hard to meet and comply with.

Nevertheless, IT companies are striving to ease the complexity behind various planning and are creating systems that reduce the weight of the clinical trial management. Such systems are of course the clinical trial management systems (CTMS) like Clinicubes. Created and developed by BGO Software, it has the effective tools to entirely handle the complexity of the clinical trial. User friendly, lightweight, and entirely customizable are among its benefits. The system aims to increase the productivity of the clinical research site and the number of successfully completed trials, and streamlines the entire clinical trial process.

Become our partner

We are currently looking for partners for the implementation and customization of Clinicubes. Get in touch and take advantage of what our clinical trial management system offers.

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