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Perfectly on Time: Successfully Managing Clinical Trial Deliverables

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Introduction

A key skill for clinical Project Managers (PM) is time management. As a PM, you are not only responsible for the project deliverables, but for every person involved as well as every task performed. Yes, it is a team effort however, in the end, the PM is the one responsible for delivering successfully on the Sponsor's expectations, from the smallest details to the general processes.

There are many strategies to help with time management that are available in a PM's toolbox, but if they were easy to implement, we as an industry wouldn't still be struggling with it. Part of this struggle comes from the fact that humans and systems have the tendency to follow the easiest path of no resistance. For our brain, resistance is something that requires effort, and therefore it becomes relentless and demands time. A natural reaction is to ignore or postpone certain obstacles and focus on activities we are more familiar with. As a result, we end up wasting time and not meeting the expected project milestones.



Resistance becomes our roadblock. If we could anticipate obstacles before they occur, we would increase the chances of avoiding problems, leading to attainable goals and solutions. So, the question becomes "How can we lower or eliminate the resistance to reaching our goals, or in other words, how can we avoid the roadblocks to delivering successful projects?" The first step is to identify them: it is important to know what issues will prevent you from successfully delivering the project whether they are intrinsic to it or not. In this White Paper, we discuss some of the roadblocks related to a typical clinical trial and some related to us, as individuals, as well as some strategies that will help you to mitigate them and better manage your time.



Roadblock #1: Lack of Project Knowledge

Each clinical study has different and unique requirements. Knowing the scope, background, and details of your project and, even more important, understanding it, is fundamental and will help you to avoid wasting time while managing the different components of the project. Something that has helped our project management team (and something that we, as a CRO, encourage them to do often) is ask lots of questions and challenge different parts of the protocol prior to study start-up or even during the proposal building stage. Here are some typical questions we ask ourselves (or the Sponsor):

- **“Do we have experience with this client?”** Knowing your client will help you to know what to expect from them and what they expect from you. And if you do not have any experience with the client, it is important to get to know them to avoid wasting time performing activities that are not required or waiting for unnecessary answers.
- **“Do we have any information about the Investigational Product (IP) that could potentially become an issue for the project?”** Many issues may be unexpected but being familiar with the IP is a fundamental part of the safety and well-being of the study participants. Although the ultimate responsibility for this aspect lies with the Investigator, as a PM your leadership is an essential component to supporting every member of the team including the Investigators.
- **“Have we (or the Sponsor) worked in the past with the sites planned for the project and how was the experience?”** Using past experiences and previous information is a great way to determine the issues you might encounter. If your team has performed “lessons learned” meetings for past studies, go back into those notes and take away key determinants for future success.
- **“What are your study milestones (i.e. expected deliverables based on realistic timelines)?”** This is a critical aspect where you should do everything possible to avoid issues. Having user-friendly electronic systems to document key information, providing adequate training, setting clear procedures, and monitoring them, is crucial to successfully managing your critical data.

Roadblock #2: Project Resources

“Do you have too many or too few people assigned to your project?” “How many Full Time Equivalents (FTEs) are required?” Having too many people involved in some of the processes might cause delays or miscommunications as well as a negative impact on your budget (i.e. too many chefs in the kitchen). Not having enough members in your team could potentially lead to activities not being performed, people being overloaded, decrease in motivation, and less performance overall. Therefore, a good analysis of the resources and assigning them properly - and at the right time - to the tasks is a fundamental part of achieving a smooth and successful project. Likewise, discussing all those questions with your team will help you not only to find the solutions but also to make sure deliverables are on target.



Roadblock #3: Lack of Planning and Organization

Planning and organization allow us to convert targets into achievements. In fact, by planning properly and organizing your daily activities you can know what to expect and, more important, when to expect it, which is a key to success in time management. However, many people struggle with these areas regardless of their role or education. Part of the issue is that most of the time we rely on our brains to remember important dates or deadlines. The problem with that is that our brains are receiving tons of information daily that needs to be processed, and we are prioritizing them automatically on a sub-conscious level, without thinking of all the consequences. This level of information sorting gets even more complicated when, let's face it, you are assigned to several projects at once. Therefore, you usually end up missing important deadlines. The good news is that planning and organization can be cultivated and with the proper tools, you can be on top of things to avoid unnecessary stress, and get your activities performed on time. These tools help to decrease the burden of stress on your own brain and transfer the load onto helpful systems you can tap into. Some of the tools available to manage your time effectively are Gantt Charts or Work Breakdown Structures (WBS), Clinical Trial Management Systems, and team communication systems (such as Slack, Microsoft Teams, etc). By using these tools, you will be able not only to visualize the project timeline but also the dependencies and the critical paths, as well as communicate in a timely manner with key project staff. In other words, it will help you to keep your project on track.

Roadblock #4: Delegation of Tasks

As human beings, there is a limited amount of work we can perform at a given time. Therefore, delegation is another vital time management skill. As a PM you need to be able to focus on high-value activities and assign tasks to your team members while you keep them engaged and help them to build their autonomy. In fact, when delegation is done properly, it is a win-win situation for all involved. However, you need to keep in mind some factors when delegating, such as training, responsibilities, workload, personal skills, and most importantly whether the tasks should be delegated or not. Another key point when delegating is transmitting a clear message, articulating the desired outcome, and making those you delegate to accountable for their deliverables. Making sure all members are on the same page will help you to avoid misunderstandings as well as wasting time.

Roadblock #5: Lack of Structure

Having a structure and routine can be helpful at any time, in particular, if you are assigned to several projects or tasks to focus on. In fact, following your daily structure or routine will help you to get right to the tasks at a given moment rather than frittering away time to get started. This ultimately helps you to get your project on track. When you are not used to structures or routines, it might be difficult to create them or even follow them. But if you know this is something you struggle with, you can observe how your peers work; is there anyone around you who could help you to build them? Or could your manager support you and help you to improve in this aspect? Asking for help and following a model that you could eventually adapt to can be the beginning of developing a very useful skill.



Final Thoughts



At Vantage BioTrials (VBT), we are familiar with the roadblocks previously mentioned and continuously implement solutions that work within our operational structure. For example, to help our team as well as our clients to better understand the essential components of the projects, we make use of tools such as SmartSheet which allows us to update, track and access our projects' data in real-time. We also use project peer assignments, so our employees can benefit from learning from more senior members on how to create an effective project workflow or how to delegate effectively. In addition, we utilize strategic planning through the use of

Quality by Design (QbD) methodologies in order to identify risk factors early on and throughout the project lifespan and mitigate those risks continuously, all with the goal of successfully delivering our projects on budget and on time.

About Vantage BioTrials

Vantage BioTrials is a leading Canadian Contract Research Organization (CRO) with over 15 years of successful projects delivered on time and on budget. We use innovative clinical trial management strategies for the life science industry with a focus on patient safety & advancing new therapies to market. We offer pharmaceutical, biotech & medical device companies a complete and integrated set of full-service clinical trial management solutions, based on the principles of Quality by Design and Risk-based clinical trial management.

Contact us today at info@vantagebiotrials.com and discover how we can add value to your next clinical trial program.