

Clinical Project Management – Where Art, Science, and Craft Meet

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ABSTRACT

Effective Clinical Project Management demands a high degree of forecasting, planning, organization, coordination, and controlling, especially when overseeing multiple clinical trials. It is a balancing act of, *Art*, encouraging creativity, *Science*, with universally accepted principles, and *Craft*, making connections through experiences. In this dynamic clinical research world, it is essential to efficiently allocate resources, track progress, budget, and timelines, in real-time, and ensure compliance with regulatory standards. This paper highlights the importance of identifying goals, arranging priorities, communicating effectively with the study team members, and ultimately mastering the skill of time management & prioritization, organization, communication, and streamlining processes. This paper will focus on the utilization of various cost-effective tools and applications that organizations can adopt to help Clinical Project Managers optimize their workflows, enhance project outcomes, and contribute significantly to the advancement and success of a clinical trial.

INTRODUCTION

In order to derive maximum efficiency within a clinical trial in terms of time, costs, resources and to achieve the strongest results, our industry focus has shifted more towards dedicated Project Management support within the clinical trials landscape. Clinical Project Managers focusing on time management & prioritization, organization and communication play a vital role in the success of clinical trial management. Relying on Clinical Project Managers within and across clinical trials reduces the burden and allows Functional Leads/SMEs and Functional Managers in the Clinical Data Management, Biostatistics, Statistical Programming domains to focus on the technical aspects of a trial without having to expend considerable amounts of energy on operational aspects.



TIME MANAGEMENT & PRIORITIZATION

The intricate nature of clinical trials demands precise allocation and coordination of resources, adherence to strict timelines and budget, and seamless collaboration among various stakeholders. Timeline delays in clinical trials can have significant financial implications and hinder the delivery of potentially life-saving treatments. Therefore, Clinical

Project Managers must excel in the skill of time management & prioritization by optimizing these study timelines, allocating resources efficiently, and maintaining the integrity of research data.



There are several ways to achieve this, and for us, the most successful approach has always been to break the project into tasks, emphasizing cross functional collaboration and providing room for continuous process improvement:

1. Developing a project plan outlining project schedule and timelines.
2. Identifying and accounting for any obstacles or risks that could interfere during the progress.
3. Allocating the right skillset and quantity of resources to complete the tasks and achieving critical milestones.
4. Adherence to regulatory guidance, all while staying within the approved budget.

It is essential for Clinical Project Managers to have the ability to anticipate challenges and risks and implement contingency plans for achieving successful outcomes in the complex world of clinical research.

Smartsheet

One of the tools that provide some of these essential capabilities in time management & prioritization is Smartsheet. Smartsheet is a cloud-based platform that provides several pre-built templates to help you develop, track, manage, and report on clinical trial information in real-time by improving collaboration, ensuring secure data, and increasing visibility.



Organize & Schedule Tasks

Break down complex project timelines into manageable tasks and organize them by project phase.



Drag & Drop Gantt Bars

Easily drag and drop Gantt bars to adjust your timeline. Underlying dates automatically adjust.



Set Durations & Dependencies

Set durations for each task and then assign dependencies to ensure proper order of completion.

 Assign Tasks Set clear expectations and increase accountability by assigning tasks to individual team members.	 Import & Export Your Work Import existing work from Excel, MS Project, Google, and Trello, and, export to PDF and PNG files.	 Change Views Work how you want to by easily switching between grid, Gantt, calendar, and Kanban card views.
 View Status on Dashboards Provide stakeholders with a high-level view of key metrics and progress on real-time dashboards.	 Access Your Work on Mobile Use the Smartsheet mobile app for Android and iOS devices to access and manage work from anywhere, at any time.	 Stay Integrated Keep work connected with integrations in Smartsheet, like Google, O365, Dropbox, Salesforce, Jira, and more.
 Collaborate with Comments Track conversations right in your Gantt chart to ensure everyone is on the same page.	 Set Alerts & Reminders Automatically notify team members and stakeholders of upcoming due dates and milestones.	 Identify Critical Path Highlight critical path with the click of a button, so you know which tasks must be completed on time.
 Share with Stakeholders Share your project with internal and external stakeholders to ensure visibility.	 Store Files & Key Information Attach files and key documentation right to your Gantt chart project plan to keep details in context.	 Track Milestones Identify milestones on your Gantt chart to provide a view into progress and ensure you hit important dates.

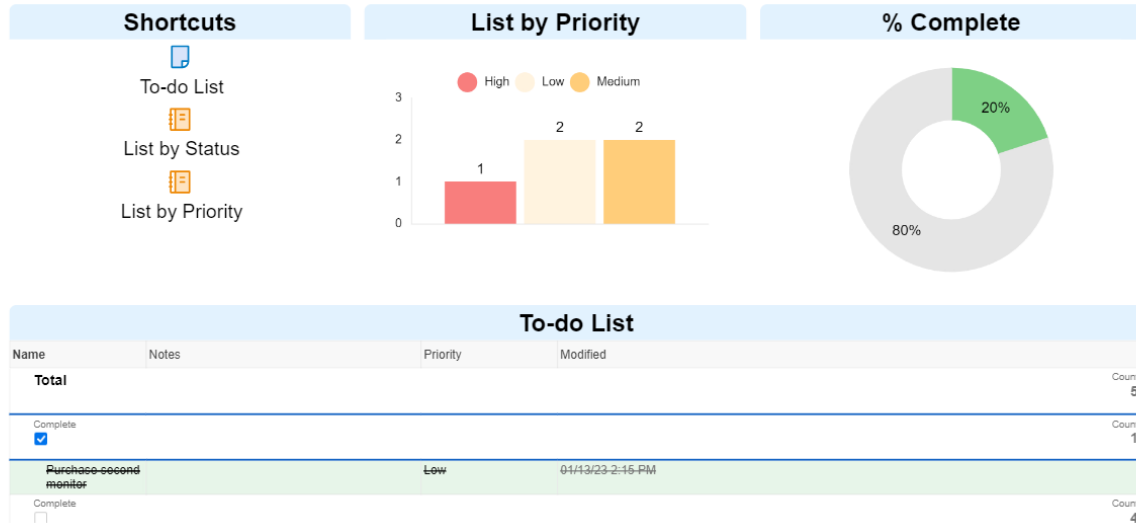
Most project teams widely use Microsoft Excel spreadsheets. Similarly, Smartsheet is a web based platform that shares comparable features and format, that is superior to Excel in work management, collaboration, visibility, accessibility, and integrations. Developing and maintaining timelines is a breeze in Smartsheet. It allows you to plan, capture, manage, automate, and report on projects and other work efficiently. Once a start and end date are filled in, “Duration” is not just automated but also sends automatic notifications to alert the team of upcoming dates, tasks, and sub-tasks. These alert notifications are not just for timelines, but any changes to the data made to the sheet is sent to a group/team of users in real-time. With the convenience of notifying users of any modifications made, it helps ensure the clinical study team and other internal and external stakeholders are simultaneously aligned and up to date on the latest deadlines throughout the life of the clinical trial.

Smartsheet also allows effective resource utilization and allocation to projects/tasks, tracking their progress and monitoring their utilization rates. This allows the Project Management team to visually see who is available at any given time and who may be over utilized.

Smartsheet also offers a diverse range of pre-designed templates to enhance project time management. Some of these templates include a straightforward To-Do List, a comprehensive Project Plan, a detailed Project Work Breakdown Structure, a Task List sorted by Priority, and a robust Project Schedule Management template. These templates range from low to high complexity depending on the needs of your project. A helpful tool within these templates is the auto-creation of visual dashboards for each desired template. The dashboards act as a visual aid to clearly see the status of your project, timeline, or task list.

Summary Dashboard

Task List by Priority



Mastering time management & prioritization skills are critical in successful Clinical Project Management. Efficiently allocating resources, setting priorities, and adhering to timelines are pivotal for the success of clinical trials. These practices ensure that tasks are completed in a timely manner, preventing delays that could impact project outcomes negatively. Effective tools like Smartsheet play a crucial role in successful time management & prioritization by streamlining workflows, helping teams prioritize tasks based on their impact and urgency and ultimately contributing to the success of clinical trials.

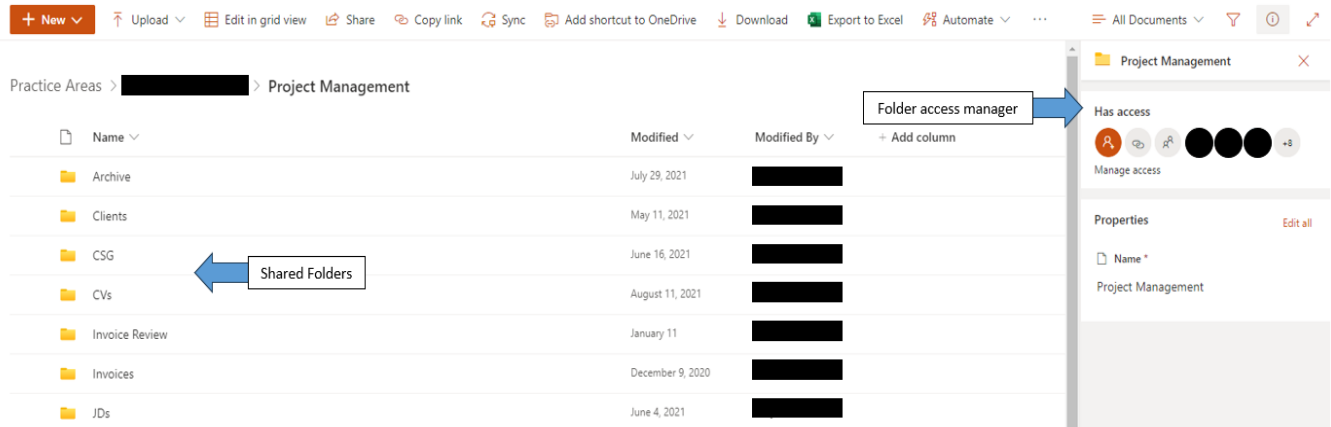
ORGANIZATION

In the realm of clinical trials, organization stands as a cornerstone for effective Project Management. As a Clinical Project Manager, careful organization is vital due to the intricate nature of clinical trials, where precise coordination, tracking and documentation are essential. Maintaining a well-organized approach ensures that team members understand their roles, tasks are executed in a coordinated manner, and deadlines are met. It allows for the identification and mitigation of potential risks, promotes clear communication, and enhances overall project transparency. Ultimately, the importance of organization for any Project Manager lies in its capacity to streamline processes, minimize errors, and maximize the likelihood of project success.

SharePoint

One of the tools that help aid in organization and streamlining processes is SharePoint. SharePoint is a cloud based service hosted by Microsoft that serves as a multi-layered repository, that is used to store, organize, share, and access information from any device with a web browser. SharePoint allows seamless collaboration between team members and allows the team to not only access documents but also engage in simultaneous viewing and editing, enhancing real-time collaboration.

SharePoint has also been risk assessed and adheres to all data security guidelines, making it a secure place to store sensitive information. With the extensive abilities SharePoint offers in terms of access, you are able to manage who has access to specific folders to ensure the confidentiality and integrity of certain documents is maintained ensuring sensitive information is shared with caution.



Additionally, SharePoint streamlines document maintenance and review processes. Through its version control features, updates to any document are systematically tracked and archived in the document history. This not only minimizes the abundance of multiple document versions but also diminishes the practice of circulating files via email for multiple reviews and updates. Subsequently, SharePoint acts not just as a collaborative platform but also as a tool of version control, promoting efficiency and acting as the organizational backbone of Project Management organization.

Microsoft Excel

Another tool that is a pivotal asset for maintaining organization in Project Management is Microsoft Excel (Excel). Excel serves as a versatile organizational tool for Project Managers, offering a structured platform to streamline project-related tasks and information. Its grid layout facilitates the creation of comprehensive task lists, timelines, budget statuses, and resource allocation charts, providing a clear overview of project components. Conditional formatting aids in visually highlighting key elements such as deadlines and task status, ensuring that potential issues are promptly identified. The ability to create Gantt charts within Excel allows Project Managers to visually represent project timelines, dependencies, and milestones. Additionally, Excel's formula capabilities simplify budget tracking and resource management, enabling managers to calculate costs, variances, and optimize resource allocation.

Some ways that Microsoft Excel can assist a Project Manager in keeping organized throughout a project lifecycle are:

Budgeting: Excel can be helpful in budget tracking by listing expenses, burn rates, and forecasting. Formulas can calculate totals, variances, percentages, and create visual representations like charts providing a real-time overview of the project's financial health. Excel's capabilities enable you to create spreadsheets to list the exhausted amount vs. the budget remaining so you are always aware of the project's financial status. Excel also has the ability to analyze and format data from a simple data load using these built-in formulas.

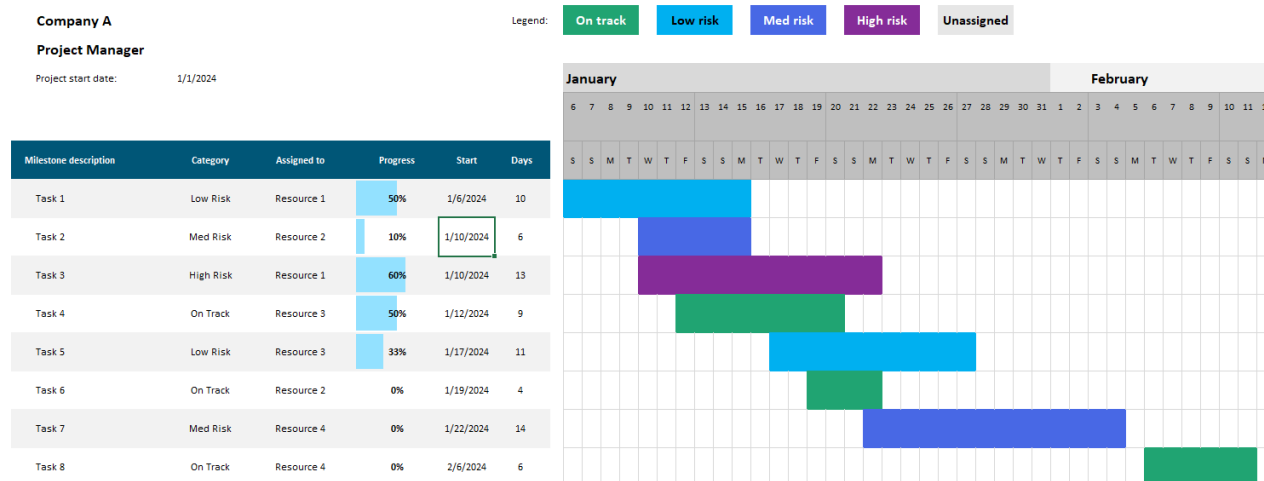


Budget Report							
Client	Project	PO #	PO Amount	Total Amount Spent	Amount Remaining	Percentage Remaining	Status
Client A	Project 1	PO 1	\$ 2,212,000.00	\$ 1,092,639.26	\$ 1,119,360.74	51%	Active
Client A	Project 2	PO 2	\$ 800,000.00	\$ 642,500.00	\$ 157,500.00	20%	Active
Client B	Project 1	PO 3	\$ 2,680,240.00	\$ 1,892,652.00	\$ 787,588.00	29%	Active
Client C	Project 1	PO 4	\$ 175,675.00	\$ 88,394.00	\$ 87,281.00	50%	Active
Client D	Project 1	PO 5	\$ 364,511.00	\$ 314,134.08	\$ 50,376.92	14%	Active
Client D	Project 2	PO 6	\$ 650,000.00	\$ 489,200.00	\$ 160,800.00	25%	Active
Client E	Project 1	PO 7	\$ 445,696.25	\$ 365,214.00	\$ 80,482.25	18%	Active
Client F	Project 1	PO 8	\$ 436,277.50	\$ 254,125.00	\$ 182,152.50	42%	Active
Client G	Project 1	PO 9	\$ 119,080.50	\$ 80,562.00	\$ 38,518.50	32%	Active
Client H	Project 1	PO 10	\$ 685,000.00	\$ 265,738.75	\$ 419,261.25	61%	Active

Resource Allocation: Excel can help aid in tracking resource usage by assigning budget, time, and personnel to tasks. Excel allows you to calculate resource costs with its numerous built in formulas, helping in budgeting and resource optimization.

Task Tracking: Excel allows creation of spreadsheets to list tasks, deadlines, and assignees using columns for task names, start/end dates, status, and responsible team members. The ability to utilize conditional formatting to highlight due dates or completion status helps in providing visual representation of the project status.

Gantt Charts: Excel's ability to create Gantt Charts using various templates helps to accurately visualize project timelines, priorities, and status. Excel's other chart functions and conditional formatting can also help represent task durations and dependencies, aiding in project scheduling and management.



Communication Log: Excel is effective in maintaining communication logs, documenting meetings, decisions, discussions, feedback, and action items. This helps in keeping a record of project discussions and ensuring everyone is on the same page.

Risk Management: You can create a risk register in Excel, outlining potential risks, their impact, probability, and mitigation plans. This provides a structured approach to handle uncertainties in the project.

Reporting: You can use Excel to generate project reports by summarizing key data using Excel's reporting tools. Customize dashboards or use PivotTables to present project status, performance metrics, and other relevant information to clients and stakeholders.

Ultimately, the collaborative nature of Excel, especially when utilized through cloud platforms such as SharePoint, fosters real-time updates and seamless communication among team members while standing as a versatile and efficient ally for Project Managers, which promotes organization, clarity, and effective decision-making throughout the project's lifecycle.

COMMUNICATION

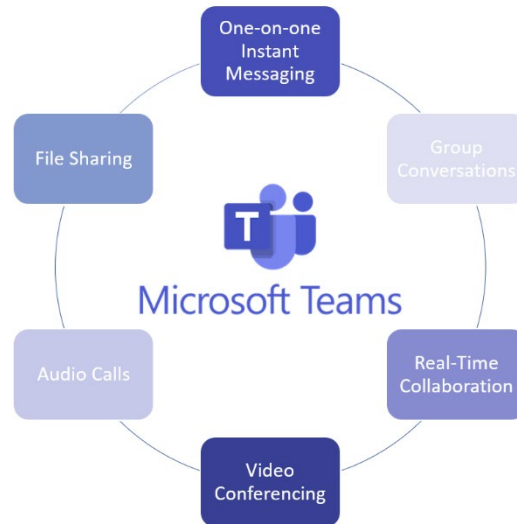
Effective communication is crucial in the landscape of Project Management within clinical trials, serving as a linchpin that promotes structure, clarity, and collaboration among team members. Clear and open communication fosters a shared understanding of project goals, timelines, and expectations, aligning the team toward a common vision. It helps in conveying roles and responsibilities, minimizing confusion and promoting accountability among team members. Additionally, effective communication promotes a positive team dynamic. Encouraging an environment where team members feel heard and supported enhances morale and motivation in the project. Effective communication also encourages feedback which enables continuous improvement, fostering a culture of learning and adaptation in the workplace.

Communication is also essential for risk mitigation, as it enables the identification and prompt addressing of potential issues and leads to a resolution in a timely manner.

In a globalized and growing virtual work environment, communication technologies and applications play a fundamental role in bridging these inevitable geographical gaps. Tools that facilitate real-time collaboration, video conferencing, and instant messaging enable efficient information exchange and effective communication.

Microsoft Teams

One tool that significantly aids in achieving effective communication is Microsoft Teams (Teams). Teams is a multi-layered, cloud based collaboration software that allows instant messaging, voice calling, video conferencing, file sharing and much more. Teams also integrates well with other Microsoft applications, specifically those mentioned earlier, SharePoint and Excel, making file sharing and collaboration seamless. No matter where your team members are located, Teams allows for instant communication around the world. And in the growing environment of remote workers, it is essential to have a platform for constant communication.



Teams allows both one-on-one instant messaging and group messaging. You are able to assign group names to different groups you are in to remain organized and pin the most important conversations to the top of your chat window. You are also able to instantly share files among team members and groups and with Teams integration capabilities, it enables simultaneous collaboration on any shared file. Teams also allows you to reply to certain chats which will create a thread for that specific conversation. This is especially helpful in group chats where team members may be having multiple conversations at a time.

In the growing world of remote work, it is essential to also be able to connect with your team or clients in a more “face to face” environment. Video conferencing facilitates seamless communication among remote teams while still maintaining a sense of connection. It enables face to face interactions, enhancing understanding and reducing miscommunication and allows for real time discussions and project updates, which promotes productivity and teamwork. With Teams video conferencing feature, it allows for this important way of communicating and Within your own account, you are able to set your status based on your availability and Teams automatically indicates you as “busy” if you have something booked on your calendar. For those times you may be away from your desk or out of the office, you are able to set away messages to anyone who may try to contact you while you are out.

Another notable feature within Teams is the ability to create and send meeting invites directly on Teams and have it automatically integrated into your Outlook calendar. When creating a meeting invite, there are several additions of what can be included apart from meeting title and attendees. You are able to include an editable agenda for the meeting attendees to view and update before the meeting time, set the meeting to automatically record, attach important files, and view the availability of other team member’s calendar who are in your organization using the scheduling assistant. In a busy work environment, the scheduling assistant is especially useful in minimizing the need to reach out to each team member individually to check for their availability. Additionally, after creating a meeting, Teams automatically creates a chat group where you are able to instantly chat with the members of the meeting.

Ultimately, effective communication is essential in successful Project Management within clinical trials. It not only establishes a foundation of structure, clarity, and collaboration but also cultivates a positive team dynamic. Utilizing tools like Microsoft Teams is pivotal in navigating the challenges of a globalized and virtual work environment. Teams facilitates seamless communication through instant messaging, group chats, file sharing, and video conferencing, promoting real-time collaboration and understanding. The platform's features, such as status indicators, away messages, and integrated calendar invites, contribute to streamlined coordination and enhanced productivity. Embracing robust communication tools like Microsoft Teams is a necessity in the evolving landscape of remote work and Project Management.

Case Study

In a recent project, the successful outcome heavily relied on effective time management & prioritization, organization, and communication. Utilizing Smartsheet to develop and maintain timelines and efficiently allocate resources greatly aided in identifying priorities throughout the project, monitoring utilization rates and tracking the progress of each deliverable. By being able to track these metrics simultaneously, it allowed us to see who was available at any given time and add resources as needed in order to meet important deadlines.

The utilization of Excel was extremely helpful when it came to tracking project budgets. By using a data download from our timesheet system, we were able to track the exhausted amount against the budget, which gave us the funds remaining. Knowing how many resources are assigned to the project from our resource utilization sheet in Smartsheet and also understanding the remaining budget available from our Excel spreadsheet, we were able to forecast if the deliverables will be completed on time and when the budget will diminish. By being able to provide this information on a weekly basis, it eased the minds of our clients, letting them know that the project is on track with time and budget.

The use of SharePoint allowed for a secure way to transfer project files and deliverables. We were able to add security measures to ensure only approved personnel gained access to the shared folder that contained sensitive documents and data. This also gave the client ease of mind knowing that their clinical data was being stored and shared in a secure manner and the confidentiality and integrity was maintained.

Additionally, with a team that is located all over the world, communication was a vital part in making this project successful. The use of Microsoft Teams made communicating with the team seamless no matter where they were located. We had daily standup meetings to get status updates from the team at a time that worked for everyone in multiple time zones. The use of video conferencing enabled us to interact in a more face to face environment which promoted stronger team collaboration and understanding of project assignments. The use of video conferencing also strengthened the relationship with our client and gave us the ability to connect on a more face-to-face manner which helped in the overall success of the project.

CONCLUSION

Ultimately, in the realm of Clinical Project Management, the combination of time management & prioritization, organization, and communication stands as the fundamentals for success. Efficiently allocating resources, setting

clear priorities, maintaining meticulous organization, and fostering open communication are indispensable components. Time management ensures that tasks are completed within set timelines, crucial in the dynamic landscape of clinical trials. Prioritization guides the team toward the most impactful activities, optimizing efforts and outcomes. Organization creates a structured framework for streamlined workflows, reducing the risk of oversights or errors. Effective communication acts as the glue that binds these elements together, promoting collaboration and understanding. Utilizing these lucrative and cost-effective tools that effortlessly integrate these aspects, becomes paramount in achieving precision and excellence in Clinical Project Management. The combined effect of these principles and tools not only ensures successful project outcomes but also contributes to a resilient and adaptive Project Management approach in the ever-evolving clinical trial landscape.

CONTACT INFORMATION

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