Scientific Project Management (SPM) to Enhance Model-Informed Drug Development

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Abstract

Objectives: Often, application of quantitative techniques to inform drug development requires a multidisciplinary approach with input from data scientists, systems pharmacologists, clinicians, statisticians, and pharmacometricians, to name a few. Project leaders in this field represent a highly desired talent due to their technical expertise and ability to coordinate work in a multidisciplinary environment. Project management (PM) that imposes too much structure and strict task management offers little flexibility for scientific exploration or innovation and can stifle project flow and insight generation, especially in discovery-based projects [1]. Our objective was to refine the PM role in the scientific consulting space to optimize scientific insight, focus, and collaboration across disciplines while minimizing the distractions of administrative barriers inherent in the management of scope, schedule, and budget.
Methods: The role, skill set, and responsibilities of traditional project managers were reframed. The SPM role shifted away from a detailed task manager with rigid oversight of scope, schedule, and budget towards a consulting role on higher level tasks and dependencies, a greater role in external and internal communication and a partner with the scientific lead on project planning and risk assessment. Agile methods [2] of PM that originated in software development were adapted to the model-informed drug development (MIDD) consulting space. The SPM skills were expanded to include a service mindset, strong collaborative focus, and experience in a related scientific discipline to communicate strategically in the context of drug development. Responsibilities were also expanded to clearly communicate scientific discussions in meetings as an integral member of the project team rather than as an adjacent administrative assistant.
Results: The SPM role was refined with a clearer understanding of PM needs in the field of quantitative drug development consultation. SPMs provided more valuable support to both the project and the scientists on the team. Task management detail receded to a more milestone focus. SPMs provided baseline PM tasks tailored to the needs of the project. Scientific insight resulted from better integration with the project team, allowing for earlier discussions on risk assessment and mitigation plans, particularly during the discovery phases of a project.
Conclusions: Prioritizing higher-level, strategic objectives, risk management, and team communication over detailed task management allows SPMs to provide more valuable support to a project. This shift allows more focused, insightful, collaborative work on the part of the scientists while achieving project objectives in the drug development consulting space.

Introduction

Successful project management in a scientific consulting space requires an approach that most closely aligns with the project workflow, optimizes scientific insight, and delivers high-value results while also managing scope, schedule, and budget.
Early PM approaches for MIDD assumed distinct "waterfall" phases (**Figure 1**). This works well when each phase is distinct, subtasks are well defined, and the workflow is consistently progressing. However, it deprioritizes other factors such as the iterations and collaborations necessary for successful, high-value scientific consulting **(Figure 2)**.

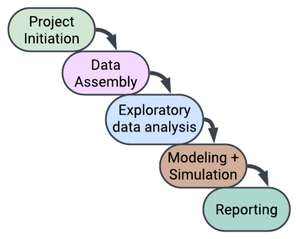

Figure 1. Waterfall workflow.

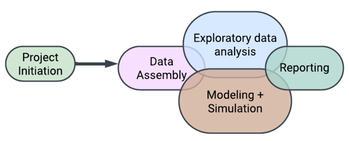

Figure 2. Collaborative workflow.

Agile methodology more closely aligns with a collaborative workflow and was implemented to promote stronger communication, better risk mitigation, and scientific exploration during, and across, project phases **(Figure 3)**. For example, during model development, a model is designed, developed, evaluated for goodness of fit, reviewed by stakeholders, and modified as needed to achieve an objective. This aligns with the plan, design, develop, test, and review phases of agile methodology.

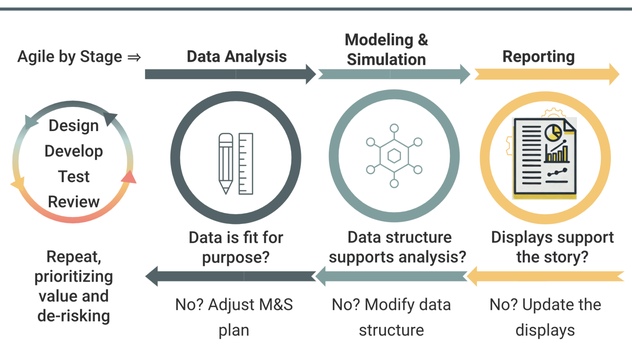

Figure 3. Agile methodology within and across stages with recursive iterations.

Traditionally, the agile approach revolves around structured task management and offers little flexibility for the exploration and innovation needed in discovery-based projects. Our objective was to refine this approach in the scientific consulting space.

Glossary

Term	Description
Agile Project Management	An iterative approach to delivering value to a project throughout its life cycle.
High-level Task	Strategic tasks that focus on broader scientific or project goals rather than day-to-day operations.
MIDD	Model-informed drug development.
Project Manager (PM)	Traditionally, the person responsible for task scheduling, budgeting, and scope management. The PM typically prioritizes timelines and resources and may be less involved in project strategy.
Risk Assessment	The process of identifying potential risks and determining their possible impact on a project.
Scientific Project Manager (SPM)	A specialized project manager with a deep understanding of scientific and strategic tasks.
Service Mindset	A philosophy that prioritizes a SPM's service to the scientific team, ensuring that the project progresses smoothly and that scientists focus on high-value tasks.
Strategic Objectives	High-level goals that align with the long-term scientific and business objectives of the project.
Task Management	The process of planning, monitoring, and controlling the tasks necessary to achieve project goals.
Value-Driven Approach	A methodology that focuses on achieving the highest value for the project stakeholders by aligning tasks and decisions with key scientific questions, long-term objectives, and maximum project impact.

Methods

The PM role was refined and shifted away from an emphasis on detailed task management to one that prioritized scientific insight, collaboration, and high-value deliverables **(Table 1)**. The SPM role retained skills involved in oversight of scope, schedule, and budget but now tailored these tasks to meet the needs of the project. Importantly, the role was expanded to include experience in the principles of scientific research or drug development. The shifts in effort were summarized following an internal subjective analysis across multiple projects and PM/SPM personnel.

Traditional Project Manager	Scientific Project Manager
Detailed task management	High-level task and dependency management
Rigid oversight of scope, schedule, budget	Partner with scientific lead on project planning and risk assessment
Structured communication planning and administrative note-taking	Focus on strong internal and external collaboration and clear communication of scientific discussions in meetings
Experience with Agile methodology	Experience in scientific discipline
Execution of project deliverables based on objectives	Partner with scientists to communicate strategically on high-value deliverables

Table 1. Shift in roles and responsibilities from traditional PM to SPM.

Results

With the traditional PM approach, the majority of the time was spent in detailed task management **(Figure 4)** with less effort devoted to the agile nature of the workflow or the scientific innovation and collaboration necessary for project success. The SPM approach shifts the work effort towards tasks that support scientific innovation and collaboration **(Figure 5)**. The shift has been well received and allows quantitative scientists to spend more time on high-value scientific problems and less time on administrative oversight.

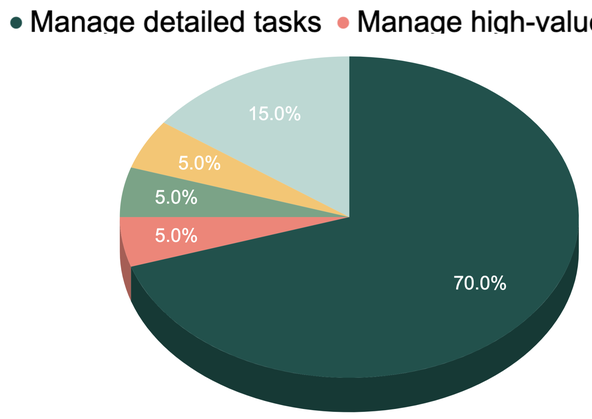

Figure 4. Work effort with a traditional Project Management role.

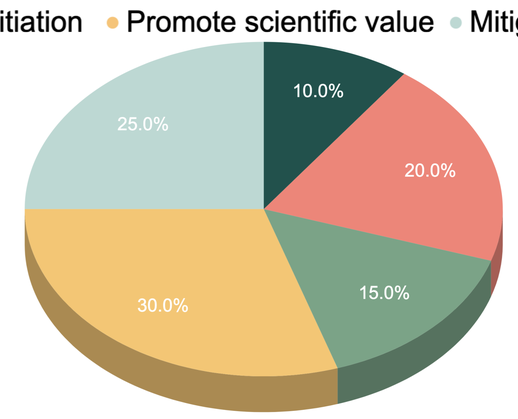

Figure 5. Work effort with a Scientific Project Management role.

The SPM focuses on promoting value-driven discussions that are more insightful for the scientific success of the project. This often uncoveres issues and risks that impact success and allows the team to openly discuss and mitigate these risks **(Table 2)**.

Tactical Questions	Value-Driven Questions
What model will be used?	Does the modeling approach address the needs or gaps in our understanding?
How long will it take to evaluate the model?	Are we using a model that is most valuable to the project? What are the risks in the most valuable model and how can we mitigate these risks?
How long would an innovative approach take vs. a more standard approach?	Are we applying the most recent knowledge towards problem solving? Have we taken the time to research this, and do we have the depth of scientific skills to apply it?
Did we plan enough time for exploratory data analysis?	Have we fully reviewed the data before modeling starts? How well do we understand the gaps? Do we understand how the data will affect model structure?
Does each scientist have sufficient time for their part of the work?	Have we fostered open communication internally and problem-solving across disciplines?

Table 2. Examples of tactical vs. value-driven discussion questions during project execution.

Positive impacts are observed for the quantitative scientists and resource leads (below). The relative effort the PM/SPM provided at different stages of the project also shifted **(Figure 6)**. With the SPM role, more time is spent during planning, initiation, and data review to de-risk issues that may affect the project objectives. Substantial time is still spent during the model and simulation phase but is focused on high-value tasks such as fostering scientific analysis and communication than on detailed task management.

Advantages of the SPM Approach

- Reduced team distractions on non-science activity
- Increased time for scientific insight and the application of innovative methodology
- Improved project organization
- Increased insightful internal and external communication and collaboration
- Improved documentation of project decision points
- Increased discussion in gaps in requirements definition, problems statements, and resourcing plan
- Increased strategic scrutiny of data to de-risk downstream negative impacts
- Promoted consultation on the risks and mitigation to high-level goals
- Promoted flexibility over structure in project workflow
- Increased focus on high-value goals vs individual tasks
- Greater strategic orientation on high-value decisions and deliverables
- Reduced time on the administrative details of resource and/or scope adjustments when needed to meet the project objectives

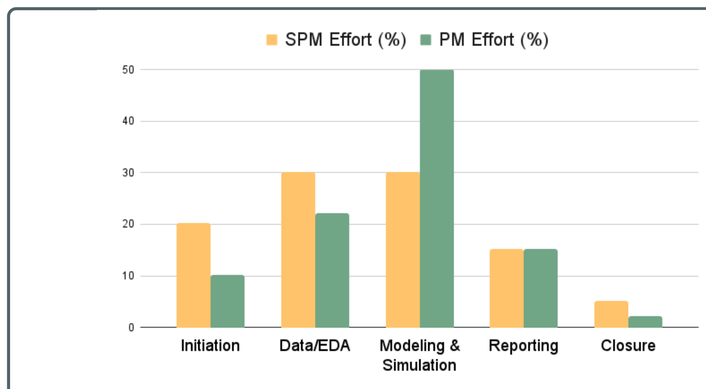

Figure 6. Comparison of effort during typical project stages.

Team Member Feedback

"The SPM straddles both worlds of the PM and the scientist, translating the scientific conversation back to matters of scope change and risk."

"The SPM has played a role in me being more strategic, thinking more about how we approach the work."

"The SPM is a true team member. There is a more meaningful relationship between scientist and the SPM."

Conclusion

Focusing on strategic, high-level objectives, effective risk management, and value-driven team communication, while minimizing the emphasis on detailed task management, enables SPMs to deliver more meaningful support for MIDD projects. This approach fosters more focused, insightful, and collaborative efforts from scientists and facilitates the achievement of key project goals in the drug development consulting space.

References

[1] Burgan, S.C. and Burgan, D.S. One size does not fit all: Choosing the right project approach. https://www.pmi.org/learning/library/choosing-right-project-approach-9346 (2014). Accessed: 2024-10-16.

[2] Principles behind the Agile Manifesto. https://agilemanifesto.org/principles.html. Accessed: 2024-10-16.

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