Cross Functional Planning, what is it?! The framework used by leading companies for effective drug development

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About the author

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Dave has worked with Life Science organizations for almost 15 years at Planisware. Dave has a wide range of experience in the Life Science PPM industry, spanning enterprise-wide life science application deployments at the largest companies in the world to 10-user implementations with smaller biotech organizations. He has expertise in integrating strategic portfolio, project, resource, and cost management into a single solution while supporting the individual needs of matrixed pharma organizations.

In his role as VP, Life Sciences PPM Practice, Dave ensures that Planisware remains the PPM tool of choice for the BioPharma industry, overseeing Planisware's life science best practices, the related product R&D, and most importantly to Planisware, its customers' successes and satisfaction.

Dave received a dual degree in Cognitive Science and in Philosophy from the University of Pennsylvania, with a concentration in Computer Science.

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EXECUTIVE SUMMARY

When it comes to designing a winning formula towards successful drug development, organizations have spent years trying to reduce inefficiencies, remain on time and within budget. For many leading organizations, Cross Functional Planning has been the positive injection required. Now becoming a common framework adopted by BioPharma and Biotech organizations, Cross-Functional Planning is the practice of managing a complex project using a single high-level, integrated plan in parallel with multiple focused functional plans. The high-level plan is strategic, long-term, and in some organizations owned by a project management office (PMO). What sets Cross Functional Planning apart from any other framework is encouraging siloed teams such as clinical, regulatory and CMC to interact with one another, helping them to reduce inefficiencies while still maintaining autonomy to get their work done. Cross Functional Planning helps improve visibility across the board, empowers functions to operate freely and helps teams share knowledge early and often. Here we share 5 key principles behind Cross Functional Planning and where to go next on your journey towards progressive drug development

INTRODUCTION

Does this sound like your organization?

A program manager has a high-level plan across phases for drug development in MS Project; clinical teams plan in Smartsheets and track execution in their CTMS, the CMC function knows what they're working on in Excel, Regulatory and Commercial teams have their own niche tool, and the rest of the non-clinical teams join team meetings but do not formally plan or track their book of work.

How about executive management who struggles to understand the current status of all programs, see the history of change (especially when one function's delay has impacted another), or have an accurate count and cumulative cost of all clinical studies?

I've seen this time and again at the organizations we work with. Different toolsets, different truths, different processes - and so much manual effort to align, collate, and report. One function becomes delayed or has a resource constraint, and nobody can easily tell how that affects everyone else in the program team.

This is exactly the set of problems that cross-functional planning is designed to solve. Cross-functional planning ensures that the high level - the integrated project plan (IPP) - is coordinated with the detailed levels - the plan from the functional teams.

1. Why Your Organization Needs Cross-Functional Planning

"The drug development enterprise has long operated in silos with limited coordination and integration among internal functions. This is exacerbated by the rising number of external service and solutions providers involved. This fragmentation manifests itself in the disparate and incompatible applications that disaggregate how data is gathered and managed."

- Ken Getz, Tufts Center for the Study of Drug Development[1]

As drug development projects grow more complex, the industry is reporting a critical need to improve information exchange.[1]

Research shows that investing in the planning process pays dividends in project outcomes. According to the Project Management Institute's (PMI) 2018 *Pulse of the Profession Report,* 9.9% of every dollar spent on a project is wasted due to poor project performance[2] - that's 99 million of every billion dollars. Take your organization's project management to the next level by implementing or refining your cross-functional planning processes (the processes by which the activities of the various functional groups are brought together to support the overall project). Sound cross-functional planning practices, supported by the right PPM tools, take the confusion out of drug development planning, integrating long-term planning with functional detail and revealing gaps and risks before they can impact your schedule and budget.

For years, we have seen large pharma organizations consider precise processes to exchange data between program leads and the functional teams. More recently, mid-sized pharma, medical device, diagnostic, and animal health organizations are picking up on the trend. These smaller organizations may not have the same depth of functional independence, but they still require concrete coordination to meet each stakeholder's needs. The transparency and control that cross-functional planning provides leads to better project outcomes and drives an organic increase in organizational maturity.

2. Principles of Cross-Functional Planning

Three principles are at the foundation of cross-functional planning excellence: A single source of truth, empowered functional teams, and effective coordination of knowledge.

In a typical organization, centralized project management offices are accountable for drug development project delivery in the long-term. The operational functions own the resources, sometimes control the budget, and are responsible for delivering on time. Figure 1 shows a project matrix for drug development. Each team contributes an important piece of the overall project plan that both drives and is driven by the planning done by other teams.

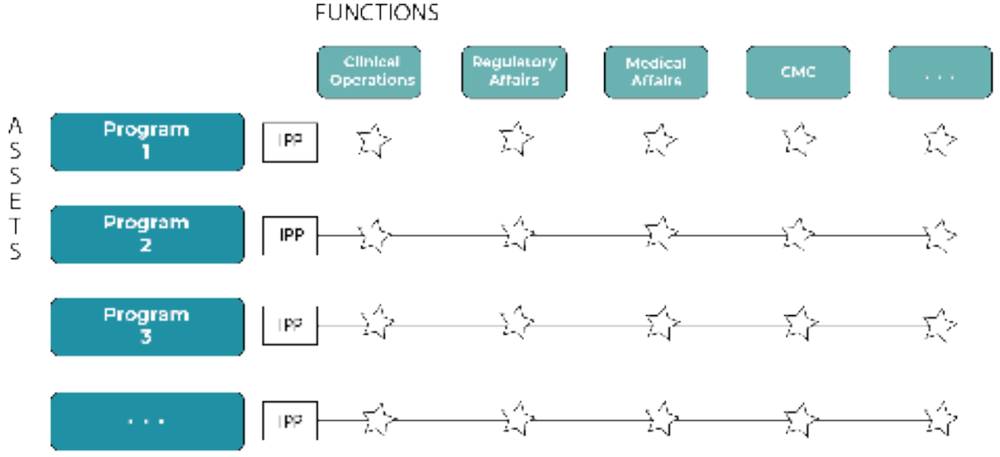

FIGURE 1: A project matrix for drug development.

With factors such as key dates, resource demand, and risks in a constant state of change, keeping everyone aligned and on track to meet obligations can be a serious challenge. To stay on track and deliver on time, teams must actively adapt their planning to account for the latest dates, constraints, and delivery targets.

How can you ensure that everyone involved has access to the consistent, accurate, and up-to-date information that they need to plan successfully? The three principles that follow provide a solid foundation for cross-functional planning.

1. Maintain a Single Source of Truth

When you need to find the latest target date for a deliverable, where do you go? Is it in an email? A spreadsheet? A PPM or study management tool? Are you sure all of your functions and your PMO are getting their information from the same place you do?

With multiple sources of information, it is easy to fall out of alignment or miss an important update. To eliminate the risk of confusion, designate and enforce a single, authoritative source of truth and ensure that all parties have appropriate access.

In a survey of workers involved in project management, 41 percent of respondents say they use several different platforms to track project data. This can cause a loss of project information, poor prioritization, and unrealistic project goals, leading to unmet expectations and missed deadlines.[3]

2. Empower Functions, Free Your PMO

It is impossible for the PMO to keep track of all the nuances that impact planning at the functional level. A PMO that tries to micromanage functional work will soon become overwhelmed. Instead, functions should be provided with clear expectations and empowered to manage their own planning, involving the PMO only when risks arise to the schedule, shared resources, or budget.

This serves the dual purpose of keeping functional plans based in reality and freeing the PMO to fulfill their primary duties: identifying and addressing risks before they become impactful and applying the latest thinking to the overall schedule.

3. Share Knowledge Early and Often

Regular communication of progress and risks from the functions allows the PMO to proactively adapt the overall project plan, pre-empting or reducing the impact of potential issues caused by functional interdependencies. Timely communication of new high-level constraints and expectations to the functions mitigates the risk of cascading delays and budgetary overages.

Is your organization good at sharing knowledge? Ask yourself the following

- Do the actions of your clinical team have unexpected impacts on other teams?
- Do your commercial teams have visibility into changes in developmental costs?
- Are your PMO's target timelines realistic and achievable from a functional perspective?

The organizations that are most effective at knowledge transfer improve project outcomes by nearly 35%. These organizations have a 20 percent increase in projects meeting original goals, a 32 percent increase in projects being completed on time, and 27 percent more projects completed within budget.[4]

3. What a Typical Cross-Functional Plan Looks Like

In a typical cross-functional set-up, a high-level Integrated Project Plan draws key information from the more detailed functional plans, simplifying strategic management while keeping a reality-based framework.

Figure 2 shows a classic cross-functional drug development plan, including clinical, nonclinical, regulatory, manufacturing, and commercial plans.

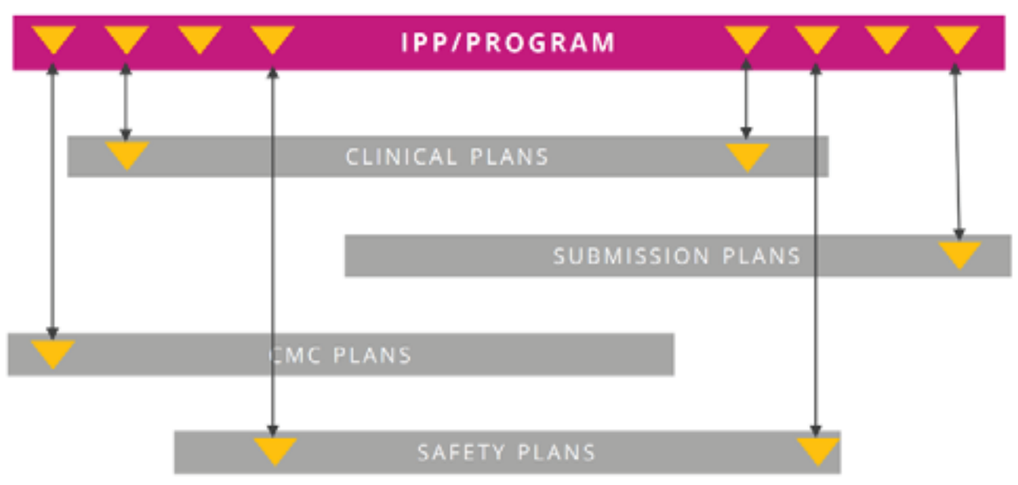

FIGURE 2: A cross-functional plan with key milestones synchronized from detailed functional level plans to the integrated project plan/program.

At the top level is the **Integrated Project Plan (IPP)**. This plan is long-term and strategic, mapping the path of the project years in advance of its execution. The IPP is typically managed by a program manager.

Some common characteristics of an IPP include:

- Full coverage of key program aspects at the cross-functional level, including expected timing, budget, and resources to support strategic analysis
- Detail sufficient for critical path analysis within each phase and across the entire IPP
- Minimal functional detail: for example, up to 20 key milestones and/or activities within a clinical study
- High-level role-based resource assignments flat-loaded between milestones

Below the IPP are the **Functional Plans**. These are created just-in-time and aim to be realistic and achievable based on actual functional timelines and constraints. The functional plans' initial timing is usually driven by the IPP's expected plan. Some common characteristics of functional plans include:

- A high level of detail: often 300 or more individual tasks and workpackages
- Monthy allocated resource estimation, sometimes down to the named resources individual level, especially for key roles within a function
- Scheduling details adjusted based on real-time feedback by the team executing the activities

The PMO works to achieve the strategic goals outlined in the IPP while adapting the schedule as needed to account for realistic budgetary, resource, and milestone information drawn from the functional plans.

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4. Use Cases

Cross-functional planning can address many of the common pain points of managing drug development projects. Consider the advantages of cross-functional planning for these typical use cases.

1. Clinical Studies

The classic example of cross-functional planning is for clinical study managers to maintain their own separate project plan, apart from the IPP, for each study. Since clinical studies make up a large percentage of a project's overall cost, streamlining data between studies and the IPP is of enormous value.

The majority of the organizations we work with who execute clinical studies plan and track these studies in a project plan separate from the overarching program. Key milestones such as First Patient In (FPI), Last Patient In (LPI), Clinical Study Report (CSR) Finalized, and so on are replicated at both the IPP level and the functional study plan level, as shown in Figure 3 below. When planned in Planisware Enterprise, the replicated milestones are kept synchronized, as they have critical impacts on the rest of the program's plan. In a typical set-up the study plan "owns" the milestones and communicates any changes to the IPP.

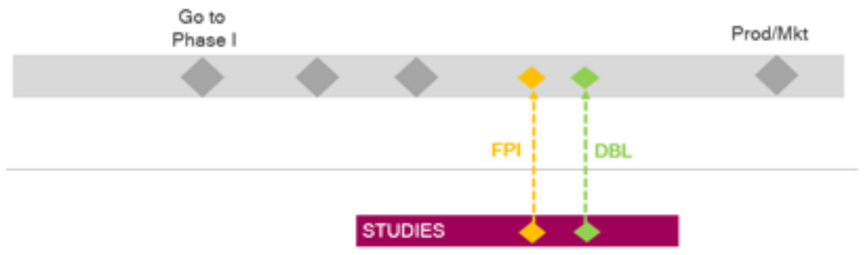

FIGURE 3: Milestones from clinical studies are replicated and typically kept synchronized in both the IPP and functional plans (i.e., a clinical study).

2. CMC: Just-In-Time Delivery

CMC timing is one of the trickier pieces of drug development planning to get right. To ensure that drugs are delivered on time, they must be manufactured in a prior phase; therefore, such work is done at risk. With a cross-functionl plan, CMC has real-time visbility into key study dates from the IPP in order to update CMC activities accordingly. The PMO, informed by both CMC's timeline and risks at the study level, can identify the precise best timing for just-in-time manufacturing.

3. Regulatory: Bundling Rules

Bundling regulatory submissions can save enormous amounts of time and money. A long-term, integrated vision of regulatory submission dates, resource needs, and available resources helps you take advantage of bundling opportunities. What-if scenario planning (enabled by PPM software such as Planisware Enterprise) enables you to set up multiple bundling options and evaluate impact before making any adjustments to your real schedule.

4. Medical Affairs: Align Tactics with Execution

Ample investment opportunities exist post-launch, with affiliates from around the globe regularly submitting ideas for how to expand on existing drug platforms. The Medical Affairs team must gather and triage study and non-study ideas, align the ideas to organizational tactics and key research questions, prioritize based on qualitative and quantitative assessments, and effectively hand off execution of selected ideas to appropriate functional teams, including clinical study teams which share resources with R&D's drug development. This process can be optimized by leveraging a PPM software platform that integrates idea management within the full project and portfolio management landscape, like Planisware Enterprise.

5. Commercial: Global Launch Planning

Commercial teams and R&D are often disconnected from each other. Cross-functional planning provides transparency to R&D around the launch plan, while ensuring that the commercial team is aware of R&D risks and ready to respond to changes in the IPP that might affect product launch dates. This is especially critical when launches will take place in multiple countries and regions, and multiple launch dates and regulatory standards are involved in the planning.

5. IT: Hybrid Agile

Software development can be the key to a successful launch of a Diagnostic or Medical Device. Set your software team up to succeed by allowing them to manage their own functional plan using Agile methodology. Critical milestones and budgetary information roll up to the IPP, just like any other functional plan.

6. External Partners & Contractors

Collaboration with external contractors can involve a large amount of overhead in both keeping your plan up to date and communicating expectations. Email exchanges and manual data transfer consume valuable time and introduce the potential for error. Instead of trying to manage external planning from the IPP, let your partners manage their own functional plan while rolling up key dates, risks, and budgetary information.

Planisware Enterprise offers an Extended Enterprise feature that allows you to create a private cloud-based environment for external resources, granting secure, controlled access to selected data.

5. The Practical Benefits of Leveraging a PPM System

As a business process, cross-functional project management streamlines planning, reducing the potential for costly setbacks and increasing the odds of success for your programs. A good PPM system can take the benefits much further.

A good cross-functional project management system, supported by carefully defined processes, brings clarity, efficiency, and resilience to the complex endeavor of drug development planning. A process-enabling PPM system like Planisware Enterprise includes comprehensive cross-functional planning features and capabilities to help your development projects operate at peak efficiency, while minimizing risk.

Listed below are some of the ways that cross-functional planning with Planisware Enterprise can help drive successful drug development at your organization:

- **Ease of use.** With Planisware Enterprise's intuitive views and data exchange mechanism, PMOs and functional planners only see the data that is important to them without sifting through information irrelevant to their work.
- **Reduced susceptibility to human error.** The increased transparency inherent to cross-functional planning reduces the potential for costly miscommunications and data inconsistencies.
- **An authoritative source of truth.** Planisware Enterprise features capabilities for all levels of the project and a range of work styles. Planning in a single system with interconnected projects ensures that dates and budgets never fall out of synchronization without a planner noticing. With a single authoritative source of data, users always know where to look for the most up-to-date information.
- **Increased efficiency.** Planisware Enterprise features tools to automatically exchange data between plans. Clean visuals and reports simplify the identification of key dependencies. Easily synchronize important information.
- **Scalability.** Planisware Enterprise's templates and libraries simplify creation of new plans and workpackages as the project progresses. The PMO can easily integrate a new plan or remove a cancelled plan at any point in the project.

At the **strategic planning** level, pivotal benefits of cross-functional planning include:

- **Long-term vision, in sync with reality.** Create long-term plans based on strategic vision and communicate important information to functions well in advance. Synchronize functional detail up progressively as it becomes relevant.
- **Clean and intuitive high-level views**. Benefit from a clear visual representation of projects, opportunities, and non-project events.
- **Simplified schedule analysis.** Targeted views and reports provide a visual representation of key interdependencies and relationships between functional plans, including new dependencies that may arise suddenly as a result of evolving functional timelines.
- **Automated monitoring.** With Planisware Enterprise, you can choose to recieve immediate notifications when functional plans fall out of synchronization with the integrated plan. The system can also highlight the potential impact of new information on the rest of the plan.
- **What-if scenario planning at every level.** Analyze the impact of planning decisions before you make them, and coordinate with all related stakeholders. Create what-if scenarios at the IPP and/or functional level to identify the best outcomes, and plan with confidence.
- **Simplified collaboration.** Easily collaborate with a wide range of stakeholders, including contract organizations (i.e., CROs or CMOs). Planisware's Extended Enterprise feature allows creation of a private, cloud-based portal for external resources with controlled access to data, removing the overhead of email communication and manual plan updates with contractors. See the latest contractor progress and risks in real-time, just like other functional plans.

At the **functional** level, advantages of cross-functional planning include:

- **Complete ownership of the functional plan.** Let functional teams plan the way that works for them, with as much detail as needed and without losing autonomy or control over execution.
- **Up-to-date information on delivery expectations.** Know immediately when changes to target dates and budgets that impact functional planning occur in the integrated project plan.
- **Higher visibility of functional needs at the IPP level.** Visibility into changing planning provides increased responsiveness to functional requests.

CONCLUSION

Where to Begin

Cross-functional planning can streamline communication and take the confusion out of project planning, reducing the risk of losing valuable development work to avoidable executional failure. So, where should you begin?

First, talk to your functions. Are they already managing their own project plans? If not, do they have a voice in the planning process? Functions that are already engaged in planning, even minimally, are your best candidates for early adoption.

Select a function that is enthusiastic about taking ownership of its plan as your pilot. Be careful to lay good foundations, but evaluate your effectiveness often and stay open to process improvements as your organization's maturity grows. As you fine-tune your processes, bring other functions onboard. Don't try to do everything at once - let viral adoption be your change management friend.

Need additional guidance? Planisware can help! Contact us at info@planisware.com to get started.

Endnotes

This whitepaper is based on a number of articles. See:

1. Jason Metthia, Applied Clinical Trials Volume 28, Issue 9, September 1, 2019 (http://www.appliedclinicaltrialsonline.com/improving-information-exchange-clinical-trials)

2. PMI's 2018 Pulse of the Profession: Success in Disruptive Times (https://www.pmi.org/-/media/pmi/documents/public/pdf/learning/thought-leadership/pulse/pulse-of-the-profession-2018.pdf)

3. Brianna Hansen, Wrike blog, Oct. 8, 2015 (https://www.wrike.com/blog/everyone-project-manager-infographic/)

4. PMI's March 2015 Pulse of the Profession: Capturing the Value of Project Management Through Knowledge Transfer (https://www.pmi.org/-/media/pmi/documents/public/pdf/learning/thought-leadership/pulse/pulse-of-the-profession-2015.pdf)

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