Roles and Responsibilities of Specialized Clinical Supply Experts

Utilizing a trial partner's clinical supply expertise helps ensure study success

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OVERVIEW

When selecting a clinical supply provider, there is a natural focus on key capabilities such as manufacturing, packaging, storage, and distribution. Often overlooked are the skills-based and knowledge-driven factors that go beyond these physical capabilities. However, these factors are integral to the development and delivery of a high-performing clinical supply chain. In practice, having a team of people with expertise in different areas of clinical supply is critical to ensuring the supply chain's overall suitability and performance. The Project Manager, Clinical Supply Manager, and Financial Project Analyst are three important roles whose responsibilities contribute to study success.

PROJECT MANAGEMENT SERVICES

Project Initiation, Planning, Execution & Control, Closing

With growing complexity in the clinical supply space and the addition of many specialty roles, it is essential that project management has a clear understanding of what is expected of them, both within the trial and as part of the wider project team. The project manager is a key team member from project initiation, through planning, to execution and control, and then closing.

Project initiation comprises a number of steps, which for a Contract Development and Manufacturing Organization (CDMO) all involve the business development function. It begins with the receipt of a Request for Proposal (RFP), triggering initial discussions of project scope and the relevant services on offer. During the creation of a proposal, which happens as the project starts to take shape, it becomes possible to identify other specialized skills and knowledge that might be required. Because they bring additional knowledge and learnings from previous studies, there is value to involving a project manager from the very start of the project, even before a contract is awarded. Once the contract is in place, best practice requires the rapid assembly of the whole project team in order to help ensure good

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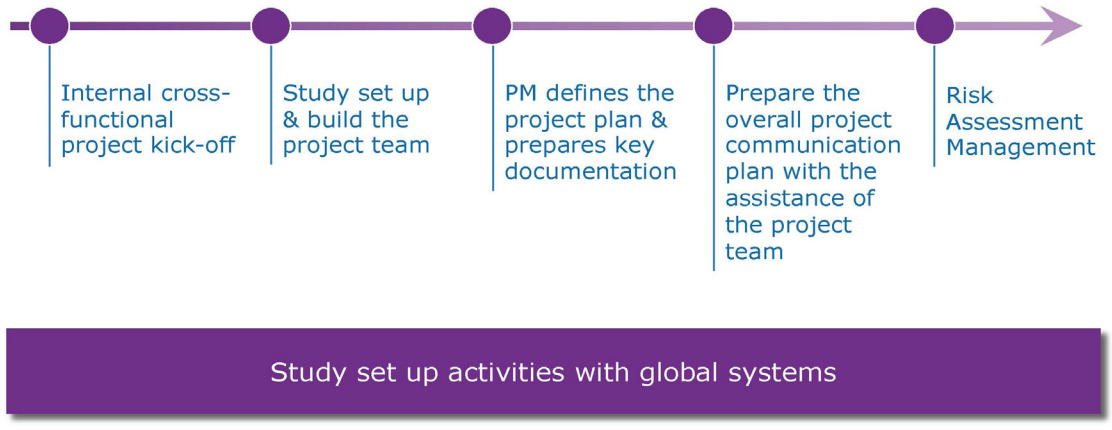
FIGURE 1: Project Management Services – Planning Phase



customer service and maximize the time available for the team to assess the project and scope, as well as gather key information before the handover from business development to project management as the project moves into the planning phase.

FIGURE 1 demonstrates typical steps in that planning phase. These begin with the internal cross-functional project kick-off meeting, the purpose of which is to ensure that all departments align on the tasks ahead and that the roles of the teams are clearly outlined. Next, during the study set-up and project team building, the scope of the project is shared with other functions and key stakeholders. This is also when key milestones, timelines, and initial risks are agreed upon and communicated. Project managers must consult the subject matter experts (SMEs) to ensure their specific knowledge and expertise will be used to help guide and de-risk the project.

The completion of set-up activities then allows the project manager to define the project plan and prepare key documentation. The project plan, usually a timeline with detailed project tasks and their dependencies, is shared with the team and the study sponsor. Completion of further key documents varies around the industry, but common themes include details around kit design, packaging, and distribution activities. Once agreed upon, these become operational documents for the set-up of activities within each of the functions to enable efficient execution.

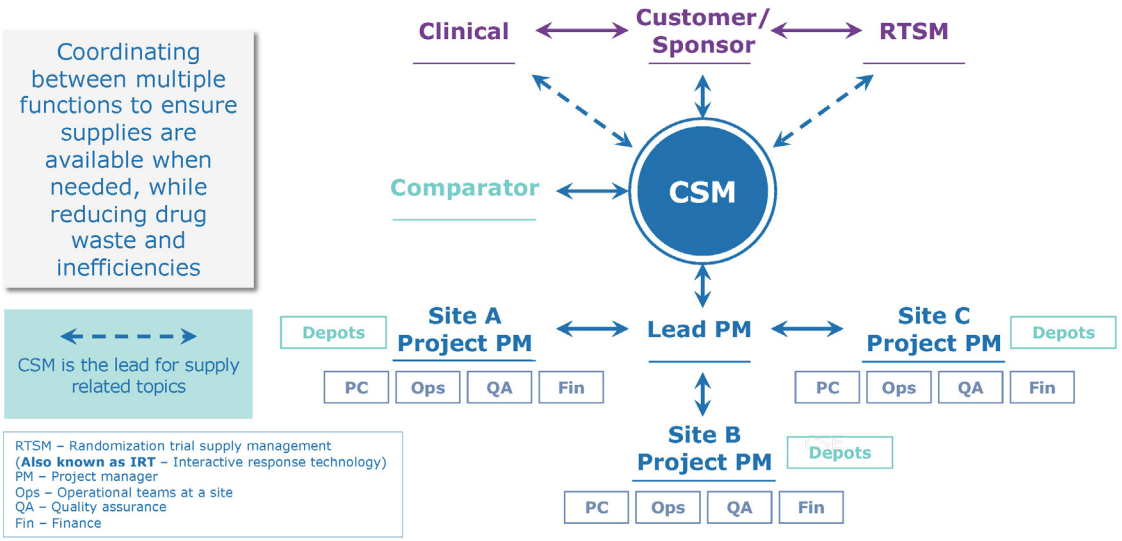
Preparation of the project communications plan, a fundamental roadmap for sharing data, information, and knowledge with the sponsor and key stakeholders, is a critically important part of the planning phase. This plan, which is put together by the project manager and supporting team, must be clear and concise and should identify a format and channels for a list of planned communications.

The ultimate step in the planning phase is preparation of risk assessment that will be used to mitigate, assign ownership, and communicate to internal and external stakeholders any potential project or timeline risks.

The next phase, execution and control, is a proactive loop that encompasses continual assessment and feedback on the project. For the project manager this means:

- Continually striving to understand the goals and manage the strategy to meet them
- Managing the overall project plan and progress to ensure that deliverables are in line with the contract, timeline, and budget
- Leading the performance of the project tasks in line with the scope of work
- Scheduling, monitoring, and communicating to the

FIGURE 2: Overall Project Management Structure with CSM



project team the status of the project tasks
- Continually identifying project risks, recognition, and proactive response
- Acting as a focal point for all internal and external communications

Active management of the risks, timelines, and key deliverables is crucial and requires assertive, proactive, and effective interactions, both internally and externally.

Finally, in parallel with managing the operational close-out of the clinical study, there is the opportunity for the project manager during the closing phase to consolidate feedback from the study and assimilate it into the organization for continuous improvement. Together with reviews of processes, this helps achieve better standardization and process improvements for future work.

CLINICAL SUPPLY MANAGEMENT

Clinical supply management (CSM) provides a service, expertise, and resource beyond project management. It combines the experience of drug supply professionals with simulation and forecasting capabilities that support the study from the initial strategy development to final drug accountability. **FIGURE 2** illustrates the relationship between project management and CSM, demonstrating that the CSM is central to all roles related to drug supply activities. The CSM interacts with the:

- Clinical Team
- Customer and sponsor
- Chemistry, manufacturing, and controls (CMC) team responsible for producing the investigational medicinal product (IMP)
- Interactive response technology (IRT)/randomization and trial supply management (RTSM) provider
- Other suppliers
- Project managers implementing the plan for product packaging and distribution

The CSM is especially important in the procurement of expensive products, ensuring their efficient use, and maintaining sufficient supply in the right places at the right times. When contracting a clinical trial, the assumption might be that the role of estimating how much drug will be needed is fulfilled by, for example, the project manager. However, it is important to consider who has end-to-end responsibility for the entire supply chain and who will fulfil the role of an

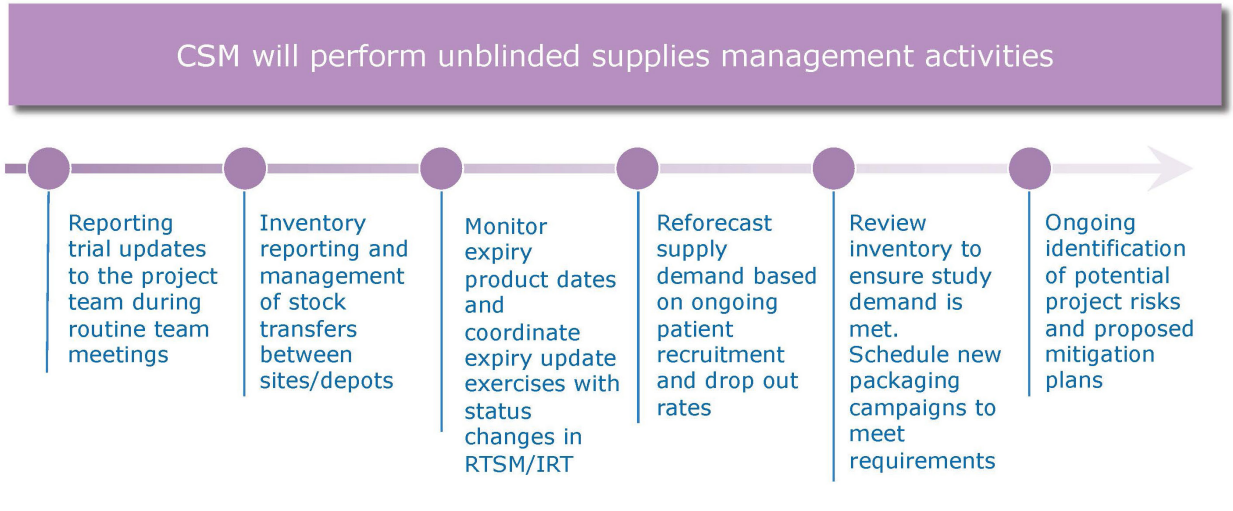
unblinded supply manager. A good CSM operates throughout all phases of a study—strategic, planning, execution and control, and closing phases.

In the strategic phase, involvement of the CSM during the early design of the study helps with planning and developing the clinical supply needs and implementing risk reduction strategies. Steps in informing decisions will include a comprehensive protocol review and a review of the IMPs, including any other comparator or ancillary requirements. The CSM will seek to understand the initial demand, the number of patients and countries involved, how the drug is dosed, and potential titrations and variabilities, then will define the packaging and labelling requirements necessary to support patient compliance. Making sure that the drug is easy for the patient to take and is in an appropriate container is important in any study. Any blinding must be factored in as well. The CSM will review information related to forecasting—for example, site initiation schedule, first patient in, and last patient out—together with product availability and expiry dates for both investigational drug product and comparators. This enables development of an initial supply and demand forecast and a communications plan related to management of supplies.

Moving into the planning phase, the CSM will plan the initial quantities of drug supply that will be sent to each clinical site and depot. They will then determine any changes from the original strategic assumptions and will plan packaging campaigns against timelines for planned and actual patient recruitment into the study. The CSM will be involved in implementing IRT/RTSM system requirements, defining user requirements, and conducting user acceptance testing to ensure that any unblinded information is available only to the appropriate managers, and will confirm that the drugs are blinded where necessary and shipment sizes are appropriate. They will review and, if required, amend these specifications throughout the study lifecycle and plan for the return of surplus kits upon completion. It is also their role to create a distribution strategy that optimizes the supply chain and, as the study progresses, to produce detailed demand forecasts. They will provide input for inclusion in the pharmacy manual, provide clinical research associate (CRA) training, and will attend investigator meetings to provide investigational product overviews.

During the execution and controlling phase, the CSM performs unblinded supplies management activities, as shown in **FIGURE 3**, working with different partners to obtain up-to-

FIGURE 3: Clinical Supplies Management – Execution & Controlling Phase



date information on the study. It is during this phase that the CSM will determine, for example, whether there are any changes in patient numbers that will affect the quantity of drugs required. The CSM assesses plans against supplies and will make any necessary adjustments. Here, monitoring expiry dates and ensuring any planned retesting is timed in accordance with current drug expiry dates to help keep sites supplied. The CSM also looks for any new risks and will consider potential mitigating actions. CSMs also function as the person who escalates any queries that relate to drug supply.

In the closing phase of a study, the CSM will work to bring the supply activities to a close by managing drug returns, stock reconciliation, accountability, and final destruction. They will coordinate the return of study drugs from sites that are scheduled for deactivation to avoid unnecessary wastage and shipments.

THE FINANCIAL PROJECT ANALYST

Financial project analysts (FPAs) have become an integral part of clinical study project teams. They contribute to the increased financial health and overall success of a project by understanding clinical trials and the risks and variables that can affect the study budget. They have the capacity to budget, forecast, and control costs through each study phase and provide clear, concise financial data needed for informed project and strategy decisions.

FPAs also provide budget analyses for alternative project scenarios and illustrate the impact on overall project costs. Their role includes working closely with operational departments and continuous improvement to identify cost savings within a project. The FPA delivers comprehensive management of all financial aspects related to a clinical trial. The following two case studies illustrate the impact of this type of financial analysis.

Case Study 1: Overcoming Inventory and Destruction Challenges for a Global Study

Two years into a complex global study, a Catalent customer experienced recruitment challenges because of the COVID-19 pandemic (see **FIGURE 4**). The study took longer than expected to complete, resulting in budgetary constraints, and a stock expiry event added further financial pressure. Together, the FPA and CSM reviewed the storage locations and expired stock and timeframes for cost-effective destruction. The FPA used scenario analysis and forecasting to develop a proactive destruction plan that reduced overall storage costs and created additional savings that enabled completion of the study with optimized use of the remaining budget.

FIGURE 4: Case Study 1: Overcoming Inventory and Destruction Challenges for a Global Study

The Challenge	The Catalent Solution	The Outcome
A customer approached Catalent when they ran into budget restraints and recruitment challenges during the Covid pandemic. Stock issues that were causing expiry events and budget challenges (due to changes) required the creation of savings two years into a complex global study.	Catalent's Financial Project Analyst and Clinical Supply Manager reviewed storage locations and expired stock in conjunction with cost-effective time frames to conduct destructions. The Financial Project Analyst developed forecasts and scenario analysis to support proactive destructions planning and cost savings.	By using scenario analysis and forecasting, Catalent reduced the overall storage cost by adding a second destruction run to several depots to complete the study and improve budget utilisation. Catalent's Financial Project Analyst created additional savings and optimised the storage of expired stock and returns.

FIGURE 5: Case Study 2: Monthly Accruals

The Challenge	The Catalent Solution	The Outcome
A customer was having challenges accruing for third-party billing and approached Catalent when they ran into accounting challenges from third-party pass-through cost.	Catalent's Financial Project Analyst reconciled all forecasted costs against planned and actual activity. In collaboration with Catalent's and the customer's finance teams, the monthly accrual was established to help the customer to plan for both month and year-end.	By using scenario-based accruals, Catalent improved the month and year-end practices of the customer and provided provisions for delayed billing. In addition, this service prevented any PO and invoice payment issues.

Case Study 2: Monthly Accruals

A Catalent customer was struggling to accrue third-party pass-through costs (see **FIGURE 5**). The FPA reconciled all forecasted costs against the planned activity. Using scenario-based accruals, they established a monthly accrual that helped the customer improve both month and year-end practices.

WORKING AS A TEAM TO SUPPORT PROJECT NEEDS

Clinical trials are complex undertakings that involve an increasing array of specialized knowledge, particularly as they move into later phases. In clinical supply, it pays to have a team of individuals with specialized expertise in the key areas of a clinical trial, from protocol review and early operational planning, to managing the development and execution of a sound clinical supply strategy. The close-working relationships of the project manager, clinical supply manager, and financial project analyst are summarized in **FIGURE 6**. Effective communication is vital. Better outcomes are associated with regular updates and interactions that occur during the different phases.

FIGURE 6: Project Manager, Clinical Supply Manager, and Financial Project Analyst...Working Together as a Team to Support Project Needs

	Planning & Set-Up	Packaging	Active Trial	Close-Out
Project Manager	• Packaging requirements, timelines & summaries • Depot set up • Label text • Randomisation	• Batch record creation & execution • Timeline management • Release • Distribution	• Provision of reports • Liaison & issue resolution (GMP) • Distribution	• Destruction facilitation (Catalent & depot)
Clinical Supply Manager	• Packaging and supply chain strategies • Simulation, forecasting & supply planning • IRT set up (URS) • IRT testing (UAT)	• Manage drug release process and availability of materials in depots and IRT system • Distribution logistics	• Inventory management • Reforecasting/revised projections/simulations • Expiry update management • Liaison & issue resolution (GCP)	• GCP final reconciliation • Destruction facilitation (clinical sites)
ADDED FINANCE LAYER				
Financial Project Analyst	• Forecasting • Cost projection	• Revise cost projections • Scenario & spend analysis • Budget control • Cost investigation • Data visualisation • Budget tracking • Cost saving initiatives		• Review of spend history • Coordinate final invoicing