Module XIV – Resourcing and Project Management in Pharmacovigilance

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1. Request for Proposal:

What is a Request for Proposal?

A request for proposal (RFP) is a solicitation made, often through a bidding process, by an agency or company interested in procurement of a commodity, service or asset, to potential suppliers to submit business proposals. It is submitted early in the procurement cycle, either at the preliminary study, or procurement stage. The RFP process brings structure to the procurement decision and is meant to allow the risks and benefits to be identified clearly up front.

Do you need an RFI?

A RFI (Request for Information) is a generally a precursor to a RFP (Request for Proposal). A RFI is often sufficient when you are buying a product that has limited scope of use and is not too expensive.

The advantage of a RFI is that you get an opportunity to understand the marketplace, see which vendors are serious about your business, get an overview of competing products, and help you gather product information that allows you to draft up more realistic requirements in case you want to do a full-blown RFP. When making a RFI to prospective vendors, it is important to word requirements using industry standard terms and structure that makes them recognizable to vendors. Another major advantage of a RFI is that you get a chance to shortlist potential vendors that you would like to invite to a RFP.

The drawback of a RFI is that vendors often perceive it as something the potential customer is not very serious about. Vendors would in most cases not put too much thought into their response. They may simply send you their standard pricing and brochures without paying much attention to your specific needs.

So, in summary, a RFI is a good method of testing the waters. If you have the luxury of time, then do a RFI before you do a RFP? Remember, it is always advisable to use an experienced consultant who has specific experience in putting together a RFI or RFP package.

Why an RFP needs to be initiated?

The RFP presents preliminary requirements for the commodity or service and may dictate to varying degrees the exact structure and format of the supplier's response. Effective RFPs typically reflect the strategy and short/long-term business objectives, providing detailed insight upon which suppliers will be able to offer a matching perspective.

Which points needs to be remembered before you start RFP?

- Create a wish list.
- What would your desired proposal include?
- Do you need a RFI (Request for Information)?

Create Wish List: -

In principle, an RFP:

- Informs suppliers that an organization is looking to procure and encourages them to make their best effort.
- Requires the company to specify what it proposes to purchase. If the requirements analysis has been prepared properly, it can be incorporated quite easily into the Request document.
- Alerts suppliers that the selection process is competitive.
- Allows for wide distribution and response.
- Ensures that suppliers respond factually to the identified requirements.
- Is generally expected to follow a structured evaluation and selection procedure, so that an organization can demonstrate impartiality - a crucial factor in public sector procurements.

What would your desired proposal include?

RFPs often include specifications of the item, project or service for which a proposal is requested. The more detailed the specifications, the better the chances that the proposal provided will be accurate. Generally, RFPs are sent to an approved supplier or vendor list.

The bidders return a proposal by a set date and time. Late proposals may or may not be

considered, depending on the terms of the initial RFP. The proposals are used to evaluate the suitability as a supplier, vendor, or institutional partner. Typically, organizations follow a detailed vendor screening process to short list the vendors who should be invited for further rounds of negotiation. This screening process could either be vendor scoring models or internal discussions within the buyer organization. Discussions may be held on the proposals (often to clarify technical capabilities or to note errors in a proposal or in many cases to negotiate on the price). In most instances, only selected bidders may be invited to participate in subsequent bids or may be asked to submit their best technical and financial proposal.

What does a RFP response contain?

RFP response requires the vendor to provide a detailed solution on the how the vendor proposes to deliver the services sought.

Responding to a RFP requires close coordination between the following vendor stakeholders:

1. Presales, Sales
2. Finance
3. Capability/Domain teams
4. Leadership

Some of the key determinants for the conversion of a RFP into a new business deal are:

1. Minimal business risks
2. Pricing
3. Competency
4. Vendor standing in the market place.

2. Project Management

2.1 Introduction

Project management is the process and activity of planning, organizing, motivating, and controlling resources, procedures and protocols to achieve specific goals in scientific or daily problems. A project is a temporary endeavor designed to produce a unique product, service or result with a defined beginning and end (usually time-constrained, and often constrained by funding or deliverables), undertaken to meet unique goals and objectives, typically to bring about beneficial change or added value. The temporary nature of projects stands in contrast with business as usual (or operations), which are repetitive, permanent, or semi- permanent functional activities to produce products or services. In practice, the management of these two systems is often quite different, and as such requires the development of distinct technical skills and management strategies.

The primary challenge of project management is to achieve all the project goals and objectives while honoring the preconceived constraints. The primary constraints are scope, time, quality and budget. The secondary and more ambitious challenge is to optimize the allocation of necessary inputs and integrate them to meet pre-defined objectives.

2.2 Approaches

There are several approaches to managing project activities including lean, iterative, incremental, and phased approaches.

Regardless of the methodology employed, careful consideration must be given to the overall project objectives, timeline, and cost, as well as the roles and responsibilities of all participants and stakeholders.

The Traditional approach

A traditional phased approach identifies a sequence of steps to be completed. In the "traditional approach five developmental components of a project can be distinguished:

- Initiation
- Planning and Design

- Execution
- Monitoring and Controlling
- Completion

Initiation

The initiating processes are determined by the nature and scope of the project. If this stage is not performed well, it is unlikely that the project will be successful in meeting the business' needs. The key project controls needed here are an understanding of the business environment and making sure that all necessary controls are incorporated into the project. Any deficiencies should be reported, and a recommendation should be made to fix them.

The initiating stage should include a plan that encompasses the following areas:

- analyzing the business needs/requirements in measurable goals
- reviewing of the current operations
- financial analysis of the costs and benefits including a budget
- stakeholder analysis, including users, and support personnel for the project
- project charter including costs, tasks, deliverables, and schedule

Planning and Design

After the initiation stage, the project is planned to an appropriate level of detail. The main purpose is to plan time, cost and resources adequately to estimate the work needed and to effectively manage risk during project execution. As with the Initiation process group, a failure to adequately plan greatly reduces the project's chances of successfully accomplishing its goals.

Project planning generally consists of

- determining how to plan (e.g. by level of detail or rolling wave);
- developing the scope statement;
- selecting the planning team;
- identifying deliverables and creating the work breakdown structure;
- identifying the activities needed to complete those deliverables and networking the

activities in their logical sequence;

- estimating the resource requirements for the activities;
- estimating time and cost for activities;
- developing the schedule;
- developing the budget;
- risk planning;
- Gaining formal approval to begin work.

Additional processes, such as planning for communications and for scope management, identifying roles and responsibilities, determining what to purchase for the project and holding a kick-off meeting are also generally advisable.

For new product development projects, conceptual design of the operation of the final product may be performed concurrent with the project planning activities and may help to inform the planning team when identifying deliverables and planning activities.

Pharmacovigilance Projects begin with the signing of the Scope of Work (SOW) with the Customer that documents the deliverables agreed.

In addition, following components are agreed with the Customer:

- *Service Level Agreements*
- *Effort Estimation and Team Requirements*
- *Communication Plan*
- *Oversight/Governance Model*

Execution

Executing consists of the processes used to complete the work defined in the project plan to accomplish the project's requirements. Execution process involves coordinating people and resources, as well as integrating and performing the activities of the project in accordance

with the project management plan. The deliverables are produced as outputs from the processes performed as defined in the project management plan and other frameworks that might be applicable to the type of project at hand.

Execution process group include:

- Direct and manage project execution
- Quality assurance of deliverables
- Acquire, develop and manage Project team
- Distribute information
- Manage stakeholder expectations
- Conduct procurement
- Test the deliverables against the initial design

Execution in Pharmacovigilance Projects includes:

- *Setting up infrastructure (Facility & IT), Resourcing, Hiring, Training, Sign off of resources and creation of project specific documentation as needed.*
- *Once the infrastructure needs (People, Process & Technology) are met, then the Project usually begins with a Pilot with predefined Sign Off criteria.*
- *Once the Sign Off is done – The Project is considered to have GONE LIVE!*

Monitoring and Controlling

Monitoring and controlling consists of those processes performed to observe project execution so that potential problems can be identified in a timely manner and corrective action can be taken, when necessary, to control the execution of the project. The key benefit is that project performance is observed and measured regularly to identify variances from the project management plan.

Monitoring and controlling includes:

- Measuring the ongoing project activities ('where we are');
- Monitoring the project variables (cost, effort, scope, etc.) against the project management plan and the project performance baseline (where we should be);
- Identify corrective actions to address issues and risks properly (How can we get on track again);
- Influencing the factors that could circumvent integrated change control so only approved changes are implemented.

In multi-phase projects, the monitoring and control process also provides feedback between project phases, to implement corrective or preventive actions to bring the project into compliance with the project management plan.

Project maintenance is an ongoing process, and it includes:

- Continuing support of end-users
- Correction of errors
- Updates of the software over time

Monitoring and controlling cycle

In this stage, managers should pay attention to how effectively and quickly user problems are resolved.

Over the course of any construction project, the work scope may change. Change is a normal and expected part of the construction process. Changes can be the result of necessary design modifications, differing site conditions, material availability, contractor- requested changes, value engineering and impacts from third parties, to name a few. Beyond executing the change in the field, the change normally needs to be documented to show what was constructed. This is referred to as change management. Hence, the owner usually requires a final record to show all changes or, more specifically, any change that modifies the tangible portions of the finished work. The record is made on the contract documents – usually, but not necessarily limited to, the design drawings. The end product of this effort is what the industry terms as-built drawings, or more simply, “as built.” The requirement for providing them is a norm in construction contracts.

When changes are introduced to the project, the viability of the project must be reassessed.

It is important not to lose sight of the initial goals and targets of the projects. When the changes accumulate, the forecasted result may not justify the original proposed investment in the project.

Monitoring of Pharmacovigilance Projects includes:

- *Team Management*
- *Workload Allocation*
- *Performance Assessment*
- *Customer Relationship Management*
- *Billing/Invoicing Management*
- *Issue Resolution*

Closing

Closing includes the formal acceptance of the project and the ending thereof. Administrative activities include the archiving of the files and documenting lessons learned.

This phase consists of:

- Contract closure: Complete and settle each contract (including the resolution of any open items) and close each contract applicable to the project or project phase.
- Project close: Finalize all activities across all the process groups to formally close the project or a project phase

Also included in this phase is the Post Implementation Review. This is a vital phase of the project for the project team to learn from experiences and apply to future projects.

Normally a Post Implementation Review consists of looking at things that went well and analyzing things that went bad on the project to come up with lessons learned.

2.3 Work breakdown structure

The work breakdown structure (WBS) is a tree structure that shows a subdivision of effort required to achieve an objective for example a program, project, and contract. The WBS may be hardware-, product-, service-, or process-oriented

A WBS can be developed by starting with the end objective and successively subdividing it into manageable components in terms of size, duration, and responsibility (e.g., systems, subsystems, components, tasks, sub-tasks, and work packages), which include all steps necessary to achieve the objective.

The work breakdown structure provides a common framework for the natural development of the overall planning and control of a contract and is the basis for dividing work into definable increments from which the statement of work can be developed and technical, schedule, cost, and labor hour reporting can be established.

2.4 Project management framework

The program (investment) life cycle integrates the project management and system development life cycles with the activities directly associated with system deployment and operation. By design, system operation management and related activities occur after the project is complete and are not documented within this guide.

Time Estimation in Project Management.

Why Estimate Time Accurately?

Accurate time estimation is a crucial skill in project management. Without it, you won't know how long your project will take, and you won't be able to get commitment from the people who need to sign it off.

Even more importantly for your career, sponsors often judge whether a project has succeeded or failed depending on whether it has been delivered on time and on budget. To have a chance of being successful as a project manager, you need to be able to negotiate sensible budgets

and achievable deadlines.

How to Estimate Time Accurately

Use these steps to make accurate time estimates:

Step 1: Understand What's Required

Start by identifying all the work that needs to be done within the project. Use tools such as Business Requirements Analysis , Work Breakdown Structures , Gap Analysis and Drill- Down to help you do this in sufficient detail.

As part of this, make sure that you allow time for meetings, reporting, communications, testing and other activities that are critical to the project's success. (You can find out more on these activities in our article on Project Management Phases and Processes .)

Step 2: Order These Activities

Now, list all the activities you identified in the order in which they need to happen.

At this stage, you don't need to add in how long you think activities are going to take. However, you might want to note any important deadlines. For example, you might need to get work by the finance department finished before it starts work on "Year End."

Step 3: Decide Who You Need to Involve

You can do the estimates yourself, brainstorm them as a group or ask others to contribute.

Where you can, get the help of the people who will do the work, as they are likely to have prior experience to draw upon. By involving them, they'll also take on greater ownership of the time estimates they come up with, and they'll work harder to meet them.

Step 4: Make Your Estimates

You're now ready to make your estimates. We've outlined a variety of methods below to help you do this. Whichever methods you choose, bear these basic rules in mind:

- To begin with, estimate the time needed for each task rather than for the project.
- The level of detail you need to go into depends on the circumstances. For example, you may only need a rough outline of time estimates for future project phases, but you'll probably need detailed estimates for the phase ahead.
- List all the assumptions, exclusions and constraints that are relevant; and note any data sources that you rely on. This will help you when your estimates are questioned and will also help you identify any risk areas if circumstances change.
- Assume that your resources will only be productive for 80 percent of the time. Build in time for unexpected events such as sickness, supply problems, equipment failure, accidents and emergencies, problem solving, and meetings.
- If some people are only working "part-time" on your project, bear in mind that they may lose time as they switch between their various roles.
- Remember that people are often overly optimistic and may significantly underestimate the amount of time that it will take for them to complete tasks.

Workload Allocation in Pharmacovigilance Projects is assigned either based on:

- *Case Type (Serious/Non-Serious, Post Marketing/Clinical/legal/Regulatory)*
- *Complexity (High Complex / Low Complex / By Product / By Therapeutic Area)*
- *Priority (Submission Due / Not Due)*
- *Volume Influx on a day*
- *Number of available resources on a day*

While lot of this allocation is done using tool bases algorithms; significant manual intervention is needed when there is a sudden influx of cases or when there are multiple submission priorities to be managed or when there is a short fall of resources.

Workload allocation and monitoring is typically necessary when there are extended holiday periods as Submission Compliance is a Key Performance Indicator of the Project!

Methods for Estimating Time

We'll now look at different approaches that you can use to estimate time. You'll probably find it most useful to use a mixture of these techniques.

- Bottom-Up Estimating

  Bottom-up estimating allows you to create an estimate for the project. To analyze from the "bottom up," break larger tasks down into detailed tasks, and then estimate the time needed to complete each one.

  Because you're considering each task incrementally, your estimate of the time required for each task is likely to be more accurate. You can then add up the total amount of time needed to complete the plan.

- Top-Down Estimating

  In top-down analysis, you develop an overview of the expected timeline first, using past projects or previous experience as a guide.

  It's often helpful to compare top-down estimates against your bottom-up estimates, to ensure accuracy.

- Comparative Estimating

  With comparative estimating, you look at the time it took to do similar tasks, on other projects.

  Parametric Estimating

  With this method, you estimate the time required for one deliverable; and then multiply it by the number of deliverables required.

  For example, if you need to create pages for a website, you'd estimate how much time it would take to do one page, and you'd then multiply this time by the total number of pages to be produced.

- Three-Point Estimating

  To build in a cushion for uncertainty, you can do three estimates – one for the best case, another for the worst case, and a final one for the most likely case.

  Although this approach requires additional effort to create three separate estimates, it allows you to set more reasonable expectations, based on a more realistic estimate of outcomes.

Preparing Your Schedule

Once you've estimated the time needed for each task, you can prepare your project schedule . Add your estimates to the draft activity list that you produced in the second step, above.

You can then create a Gantt chart to schedule activities and assign resources to your project; and to finalize milestones and deadlines.

What are the Uncertainty in time estimates?

- Some activities will take longer, and others will go faster expected.
- Source of uncertainty
- Varying the knowledge and skill.
- Individual difference in approaching work
- Mistakes or misunderstanding
- Unexpected events

2.5 Team Management:

Team management refers to techniques, processes and tools for organizing and coordinating a group of individuals working towards a common goal or task; i.e. a team.

There are four stages like Forming, Storming, Norming and Performing. Forming is a stage in which team members come together but may not know each other. Gathering and sharing information occur in this stage and strengths and weaknesses are gauged to determine where a person may fit in with the project. Storming is the stage where conflicts, rules, and expectations get discussed.

A leader is also chosen here. Norming occurs when bonds are created, and alliances and trust start to flourish. The members will learn how they fit into the collective goal. Performing is the first time when work begins towards the goal. It is generally the longest stage and all responsibilities have been handed down. Finally, in adjourning, the loose ends get tied up and completion tasks are finished.

While the activities of team management are not new, many of the tools used by team managers are. The more Organizational Development-oriented practitioners often use

interview-based analysis and provide reportage and insights that team leaders and their management may use to adapt team practices for higher performance.

Teams can also be developed through team building activities - which can also be used simply to build relationships where team members lack cohesion due to organizational structure or physical distance. Project managers may approach team management with a focus on structure, communications and standardized practices.

With the growing need to integrate the efforts of teams composed of members from different companies and geographies, organizations are increasingly turning to a new class of Internet software for team management. These tools combine planning and collaboration with features that provides a structure for team relationships and behaviors. In addition, there are tools that facilitate the forming of highly productive teams through analysis of personality and skills profiles.

Team skills

If you are working with or managing a team or a group of stakeholder's team management skills are essential. These skills are best acquired experientially through workshops and practice.

Other skills that are particularly useful for the Project Manager are negotiation and conflict resolution.

Refer to the Newsflash link on this site for information about the latest workshops.

Roles and Responsibilities

Definition of responsibilities for a project should occur during the planning phase. However, communication of those responsibilities must be continuous during the Implementation phase.

There should be no ambiguity about roles and responsibilities. That means responsibilities must be defined in detail.

The most useful investment of a Project Manager's time early in the Implementation phase is spent with individual project personnel to make sure they are clear about their responsibilities and have the required information and skill to carry out the work.

Typical Designations in Pharmacovigilance Projects are:

- *Safety Associate, Safety Scientist, Safety Physician, Team Leader, Manager, Senior Manager, Project Director*
- *On-site Co-Ordinator, Program Manager*
- *External stakeholders such as QA, Transition, Training, HR support new and ongoing projects on a need be basis.*

It is the responsibility of the Project Manager to:

- Identify the skills required for each part of the project.
- Locate appropriate project staff
- Arrange for training if necessary
- Keep staff up to date about any changes
- Look after the morale of the project staff

Group & Teams

Group

Two or more persons who are interacting in such a way that each person influences and is influenced by each other person.

Team

A group of people committed to a common purpose, set of performance goals, and approach for which the team members hold themselves mutually accountable.

How to build productive team

- Have clear mission / purpose.
- Set specific performance goals.
- Compose the right team size & mix.
- Have an agreed upon structure appropriate to the task.
- Delegate the authority to make the decision needed to complete the missions.
- Offer a mix of group & individual rewards.
- Foster longevity & stability of membership.

What it takes to be a team player

- Personality
- Individualism vs collectivism
- Interpersonal Skills
- Conflict Management skills
- Collaborative problem-solving skills
- Communication Skills
- Develop & establish goals
- Control, monitor, and provide feedback.
- Set work roles & assign tasks

Leading productive teams

- Team leader skills
- Coaching and not bossing
- Help define, analyze & solve problems.
- Encourage participation by others
- Serve as facilitator
- Team leader Values
- Respecting fellow team members
- Trusting fellow team members
- Putting the team first.

- *In order to enhance productivity and have better oversight - Teams are typically structed in a hierarchical fashion.*
- *The Project Members (Safety Associate, Safety Scientist, Safety Physician) report to Managers (Team Leader, Manager, Senior Manager, Project Director)*

2.6 Service Level Agreements & Transition plan

What is SLA?

A service level agreement (SLA) is a contract between a service provider (either internal or external) and the end user that defines the level of service expected from the service provider. SLAs are output-based in that their purpose is specifically to define what the customer will receive.

A service-level agreement is an agreement between two or more parties, where one is the customer and the others are service providers. This can be a legally binding formal or an informal "contract" (for example, internal department relationships). Contracts between the service provider and other third parties are often (incorrectly) called SLAs – because the level of service has been set by the (principal) customer, there can be no "agreement" between third parties; these agreements are simply "contracts." Operational-level agreements or OLAs, however, may be used by internal groups to support SLAs.

SLAs commonly include segments to address: a definition of services, performance measurement, problem management, customer duties, warranties, disaster recovery, and termination of agreement. To ensure that SLAs are consistently met, these agreements are often designed with specific lines of demarcation and the parties involved are required to meet regularly to create an open forum for communication.

Typical Service Level Agreements in Pharmacovigilance Projects

- ***Productivity***
  - *Number of Cases processes (n)*
  - *Number of Reports generated (n)*
- ***Quality***
  - *Quality Score of deliverable (%)*
- ***Compliance***
  - *Number of Deliverables reported to Regulators/Sponsors within timelines (n/%)*

Service level agreements are also defined at different levels:

- Customer-based SLA: An agreement with an individual customer group, covering all the services they use. For example, an SLA between a supplier (IT service provider) and the finance department of a large organization for the services such as finance system, payroll system, billing system, procurement/purchase system, etc.
- Service-based SLA: An agreement for all customers using the services being delivered by the service provider. For example:
  - A car service station offers a routine service to all the customers and offers certain maintenance as a part of offer with the universal charging.
  - A mobile service provider offers a routine service to all the customers and offers certain maintenance as a part of offer with the universal charging
  - An email system for the entire organization. There are chances of difficulties arising in this type of SLA as level of the services being offered may vary for different customers (for example, head office staff may use high-speed LAN connections while local offices may have to use a lower speed leased line).
- Multilevel SLA: The SLA is split into the different levels, each addressing different set of

customers for the same services, in the same SLA.

- Corporate-level SLA: Covering all the generic service level management (often abbreviated as SLM) issues appropriate to every customer throughout the organization. These issues are likely to be less volatile and so updates (SLA reviews) are less frequently required.
- Customer-level SLA: covering all SLM issues relevant to the customer group, regardless of the services being used.
- Service-level SLA: covering all SLM issue relevant to the specific services, in relation to this specific customer group.

Transition Plan

Pilot Phase

A pilot experiment, also called a pilot study, is a small scale preliminary study conducted to evaluate feasibility, time, cost, adverse events, and effects size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project. Pilot studies, therefore, may not be appropriate for case studies.

Implementation of pilot studies

Pilot experiments are frequently carried out before large-scale quantitative research, to avoid time and money being wasted on an inadequately designed project. A pilot study is usually carried out on members of the relevant population, but not on those who will form part of the final sample. This is because it may influence the later behavior of research subjects if they have already been involved in the research.

A pilot experiment/study is often used to test the design of the full-scale experiment which then can be adjusted. It is a potentially valuable insight, and should anything be missing in the pilot study it can be added to the full-scale (and more expensive) experiment to improve the chances of a clear outcome.

Go Live

The purpose of this phase is to cut over to live productive operation and to continuously support and improve live operations. The Go-Live and Support phase consists of two distinct phases. First, the project is completed with a formal "Project Closing". During this time, the system is used productively in day-to-day operations, all issues and problems are resolved, transition to the production support team finalized, knowledge transfer completed, and the project signed off. Subsequently, the "Continuous Improvement" phase begins during which the production support team monitors the system and resolves live business process issues. Proper change management procedures are established, and ongoing end user training is conducted. Plans are made to continuously review and improve business processes and the "Review and Optimization Conference" is scheduled and conducted.