



Module 14: Resourcing and Project Management in Pharmacovigilance

Request for Proposal (1)

- A RFI (Request for Information) is a precursor to a RFP
- RFI provides an opportunity to understand the marketplace and get an overview of competing products
- A request for proposal (RFP) is a solicitation made, through a bidding process, by an agency or company interested in procurement of a commodity, service or valuable asset, to potential suppliers to submit business proposals.
- 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.



Request for Proposal (2)

- 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.



Response to RFP (1)

- 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.
- 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.



Response to RFP (2)

- 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 - Presales, Sales, Finance, Capability/Domain teams and Leadership
- Some of the key determinants for the conversion of a RFP into a new business deal are - Minimal business risks, Pricing, Competency, Vendor standing in the market place.



Project Management

- 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.
- The primary challenge of project management is to achieve all the project goals and objectives while honoring the preconceived constraints.



Methods of Project Management

- **The Traditional approach**

- Initiation
- Planning and Design
- Execution
- Monitoring and Controlling
- Completion

- **Work breakdown structure**

- 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.



PV Project Management (1)

– Initiation, Planning and Design

- Begins with the signing of the Scope of Work (SOW) with the Customer which documents the deliverables agreed.
- In addition, following are the components agreed with the Customer:
 - Service Level Agreements
 - Effort Estimation and Team Requirements
 - Communication Plan
 - Oversight/Governance Model

– Execution

- The various activities included are; infrastructure set up (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!



PV Project Management (2)

– Monitoring and Controlling

Once the Project has Gone Live – Activities performed by the Project Management Team typically include:

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

– Completion

If a Project is due for closure – Adequate handover of activities through documentation and transition of work out is carried out.



Groups and Teams

- Group
 - Two or more persons who are interacting in such a way that each person influences and is influenced by the other .
- Team(s)
 - A group of people committed to a common purpose, set of performance goals, and approach for which the team members hold themselves mutually accountable.
 - 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.*



How to Build a Productive Team

- ✓ Have clear mission/purpose.
- ✓ Set specific performance goals.
- ✓ Compose the right team size and mix.
- ✓ Have an agreed-upon structure appropriate to the task.
- ✓ Delegate the authority to make the decisions needed, given their mission.
- ✓ Provide access to or control of the resources needed to complete their mission.
- ✓ Offer a mix of group and individual rewards.
- ✓ Foster longevity and stability of membership.



These guiding principles apply to all members of a project involved in managing other team members

Characteristics of High-performing Work Teams



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

These guiding principles apply to all members of a project involved in managing other team members

What It Takes to Be a Team Player

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



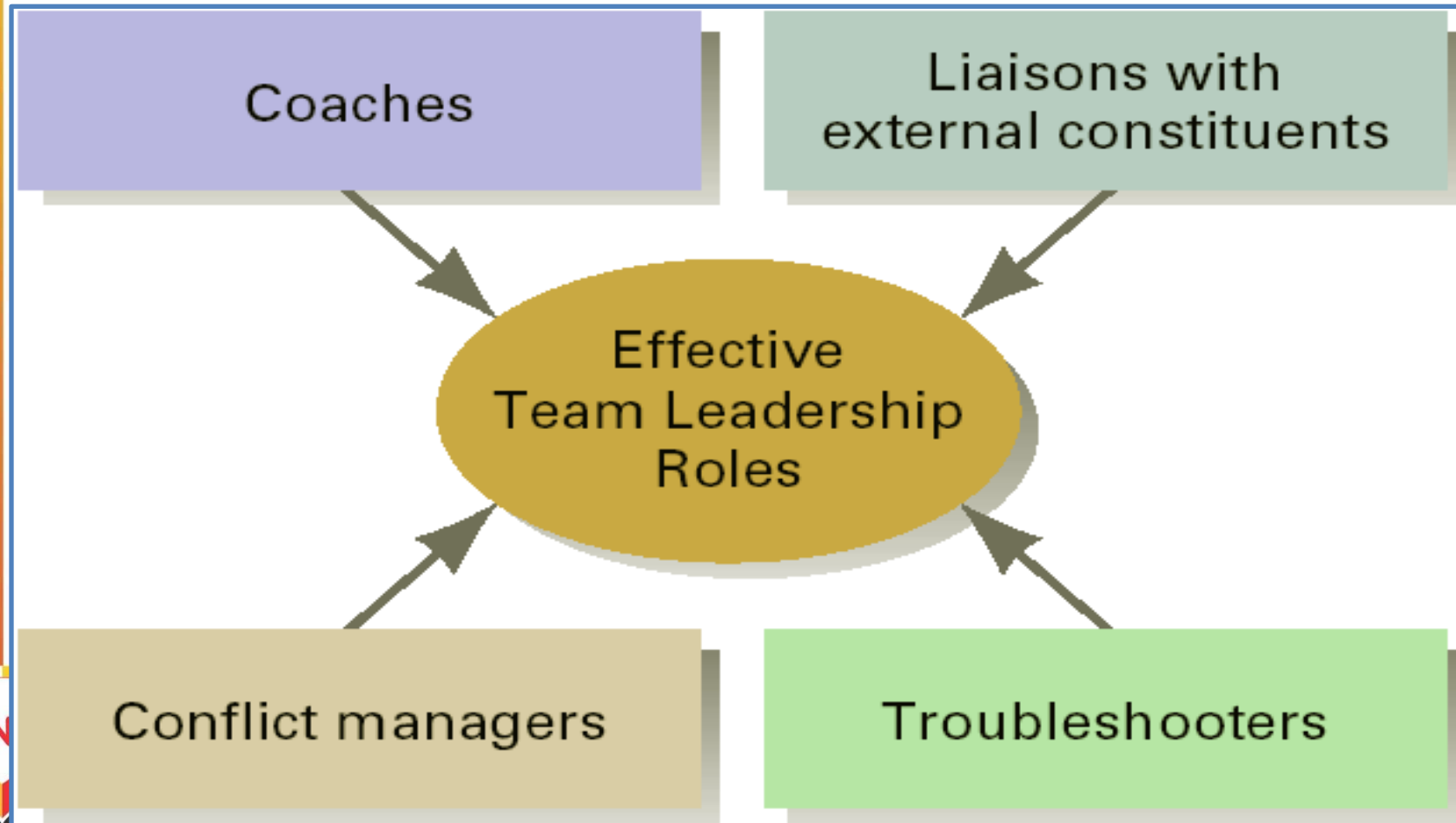
These guiding principles apply to all members of a project involved in managing other team members

Leading Productive Teams

- Manager Skills
 - Coaching, not bossing
 - Help define, analyze, and solve problems
 - Encourage participation by others
 - Serve as a facilitator
- Manager Values
 - Respecting fellow team members
 - Trusting fellow team members
 - Putting the team first



Team Leader/Manager Roles



Workload Allocation – General Principles

- Mechanism

- Defining Workflow in Database
- Appropriate allocation based on resource availability
- Monitor
- Trouble shoot

- Key Levers

- Configuration of Safety Database and Dashboards
- Prioritization of Deliverables
- Availability of Resources
- Volume Fluctuations



Workload Allocation in PV Projects

Workload Allocation is typically 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 particular day
- Number of available resources on a particular 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.

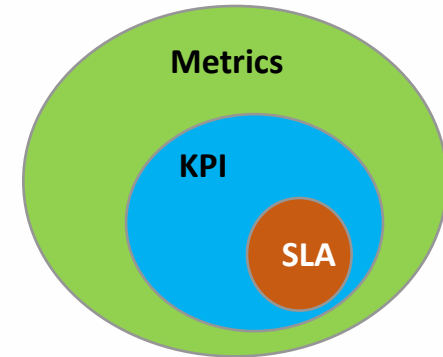
Workload allocation and monitoring is typically necessary when there are extended holiday periods as Submission Compliance is a Key Performance Indicator of the Project !



Deliverable/Metrics/KPI/SLA

Deliverable: Any artifact that is delivered to Customer. Eg. Updated database

Metrics: Metrics is the attribute of a deliverable. Any measurable attribute of inputs, activities in the process or Outputs. Eg. Accuracy of updated database Or time to update database



Key Performance Indicator: Any metrics that demonstrates the health of a process . Eg. Accuracy of updated database

Service Level Agreement (SLA): An indicator (generally for deliverable / output) on which the Customer has set a target for the supplier to achieve. Eg. Min 99% Accuracy of database

ICSR Processing Metrics & SLA

- 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/%)



Communication within Projects

- Within Teams

- Frequency (At least Daily)
- Weekly / Monthly Performance (Productivity & Quality) Ranking
- Action Items (Status of Open items and update on Closed)
- Quarterly/Annually Performance Assessments

- With Clients

- Frequency (At least Weekly or Fortnightly)
- Monthly Governance Meetings
- Action Items (Status of Open items and update on Closed)
- Annual Project Review Meeting



Thank you!

