Effective Project Leadership and Management: A CRO Perspective

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Overview

- What PM Models are utilized in a CRO?
- What factors influence the Project Leadership continuum?
- What PM traits of effectiveness are common in both Pharma and CRO space?
- What makes a CRO PM unique?
- Are there opportunities for increased joint success for the Pharma and CRO PM?

CRO Project Manager

A CRO PM manages some or all aspects of one or more drug/vaccine/device development projects for the Pharma, Biotech or generic industry with a goal to meet or exceed client expectations

- Name of positions: Project Manager, Program Manager
- Continuum of PM role into a Program Director “project champion” role

- Aspects and scope of the job may vary based on the client expectations
  - Important to define expectations of PM model needed
CRO Project Management Models

Examples in the Clin Pharm Space:

Single Drug Development Program
- Plan and manage projects/regulatory filings to move drug from discovery to clinical PoC

Phase 2a and Special Patient Population Programs
- Utilize strong working relationships with qualified specialty sites
- Program team oversees site and interactions between client and site

Portfolio of Drug Programs
- Several drugs with a common set of potential study types
- Optimized process and communications to realize efficiency and speed from outsourcing relationship
- Program Director is 'conductor' of large team and 'single accountable contact' for client

Comparison of Two Program Types

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Single Drug Development</th>
<th>Portfolio of Drugs</th>
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</thead>
<tbody>
<tr>
<td>Client Management Model</td>
<td>Program Director (PD) or PM leads program</td>
<td>PD is single point of responsibility supported by one or more PMs</td>
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<tr>
<td>Program Team</td>
<td>Subject matter experts for each area – leaner team</td>
<td>Relationship managers for several similar studies at same time</td>
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<tr>
<td>Strategy and Design</td>
<td>CRO processes/output formats</td>
<td>Customized per client</td>
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<tr>
<td>Duration Decision Making</td>
<td>CRO guides and influences, dependent on drug's survival</td>
<td>Potential for long-term business relationship</td>
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<tr>
<td>Client Goal Resolution</td>
<td>Generate real value from the drug by demonstrating PoC management</td>
<td>Generate efficiency and cost savings without losing quality and timeliness</td>
</tr>
<tr>
<td>Client focus</td>
<td>Cost and time</td>
<td>Quality and trust</td>
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An effective CRO PM uses many skillsets to drive project execution.

Characteristics of a Productive Project Team Environment

- Include and plan for a project kick off meeting and face to face meetings
- **Define the roles** and responsibilities of each team member
- Operate in a spirit of collaboration with a shared vision
- Transparent decision making; Determine how decisions will be made and roles of each team member in the process
- Spend time and energy defining objectives
- Engage and communicate actively with management
- Decide but revisit which communication tools are optimal
- Recognize and respect differences
- Plan for adversity Plan for the expected as well as the unexpected

Common Traits with the Pharma PM

- See the big picture
- Know what needs to be done and the right questions to ask!
- Be the functional integrator. Understand how each item affects the total project.
- Ability to plan for and navigate the land mines
- Determine and manage the hand offs

Common Leadership Traits

- Influence without authority
- Instill trust with style and confidence
- Motivate the team and hold them accountable
- Manage stakeholders interests by centering on the goal

Maintain focus and stay cool and objective!
A View of Leadership for Consideration
“The Functional Integrator”

The author interviewed 50 leaders and found that they all had a unique trait termed **integrative thinking**: "Ability/predisposition/capacity to hold two opposing ideas at once. Moreover, without panicking or settling for one alternative, they are able to creatively resolve the tension between those 2 ideas by generating a new one that contains elements of both but is superior to both!"

Integrative thinkers don’t break down problems into individual parts and work on them separately in a certain order. They are able to see the entire architecture of the problem, how the various parts fit together and how one decision affects another one and can hold all elements suspended at once in their minds.


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Critical Skills for a CRO PM

External and internal client to satisfy - Interface between 2 organizations

**Manage expectations and risks for internal and external customers**
- Walk the fine line between client and company advocacy
- Manage expectations between two sets of senior management
- Handle issues with respect to the regulations

**Increased number of stakeholders**
- Provide multiple solutions to different stakeholders
- Manage interactions with client outsourcing and clinical teams
- Ability and respect to share the bad news internally and externally

**Manage cultural barriers**
- Acronyms from both sides! Internal language vs. language of the client
- Different cultures, ways of thinking
- Manage to internal SOPs/guidance’s and client SOPs
2 Sets of Parallel Teams!

Client
- Executive
- Contract / Project Management
- Protocol Design
- Clinical Operations
- Bioanalysis
- Data Management & Analysis
- Medical Writing

CRO
- Executive
- ECG Core Lab
- Data Manager
- Biostatistician
- Clinical Study Manager
- Bioanalytical Principal Investigator (BPI)
- Pharmacokineticist
- Medical Writer

Project Manager
- Language “translator”
- Functional Integrator
- Streamlines communication
- Fosters appropriate direct interactions

A Key Expectation of a CRO PM

Ability to strongly partner with clients
Understanding the answer to “What does the client want”?

- A good *translator* of what the sponsor wants
  - Translate “the what” into team action
  - Client asks for “X”, in our CRO it may mean “Y”
- Ability to articulate complex items clearly for the client and management
- Chair the client meetings and provide updates on significant items at appropriate level of detail
**Environment of a CRO PM**

**Different and/or Multiple clients**

- Exposure to a greater number of drug development programs and clients; broader perspective
- Flexibility to mold to varying clients (Pharma, biotech, generic, biologics) expectations
- Changing internal team/resources to manage
- Understand and document each clients “requirements” and communication system
- Varied scope of relationship: programmatic, task oriented or a collaborative model moving towards a partnership
- Varying work load with full attention desired by client

**Requirements of a CRO PM**

**Budgetary requirements**

- Responsible for budgets and keeping projects on track financially

**Solution provider**

- Identify the gaps and find a way to fill them
- Continuous process improvement per client
- Positive reinforcement with vision towards how the team can make it easier, better, faster for the client

**Challenges and Opportunities**

- May not be aware of the big picture
- CRO measured by performance rather than compound success
- Have the patience and self discipline to stick with it!
Unique Relationship with BD

Act as a solution provider with Business Development

- Work effectively with BD to grow the business
- Serve as an extension of BD and co-own the client relationship
- **BD brings in business; Good PMs can drive business** based on customer satisfaction
- **Strategically understand the client goals**
- Shared contract responsibilities
- Contacts may be different for the BD and PM but all are equally relevant and influential

Effective PM Partnerships between CRO and Pharma

Enhance visibility of partners
- Access to people
- Proactive scheduling for a year to allow for planning / resourcing
- Forecast into the horizon

Build a Foundation of Trust
- Proactively identify problems and determine solutions together
- Focus together on continuous improvement and build upon a history of successes
- Mutual respect

Share background and drug development plans frequently
- Boosts morale and offers motivation
- Knowledge that CRO is part of something “bigger”
- Creates dedicated teams who go “above and beyond” expectations

Create Shared Ownership
- Share program goals, challenges and successes
- Clearly defined expectations
- Joint performance and quality metrics
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