



## Building First-Line Leadership in Contract Research Organizations: Senior Leaders' Perspectives on Critical Transition Competencies

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**ABSTRACT:** Transitioning from Individual Contributor (IC) to First-Line Manager (FLM) is a pivotal career shift in Contract Research Organizations (CROs), where technical excellence alone does not guarantee leadership effectiveness. In the high-stakes, highly regulated clinical research environment, failure to navigate this transition leads to significant organizational costs and risks to trial integrity. This study examines the behavioral and strategic competencies senior leaders regard as critical for successful FLM transitions and for sustaining performance in clinical research. Utilizing reflexive thematic analysis, the study draws on semi-structured interviews with 10 senior leaders across diverse CRO functions to identify patterned meanings in the accounts of effective versus struggling new managers. Six interlocking themes emerged: (1) Emotional Intelligence and Self-Management, (2) Team Building and People Management, (3) Communication and Interpersonal Skills, (4) Leadership and Strategic Skills, (5) Coaching, Mentoring, and Support Systems, and (6) Technical and Analytical Skills. Across these domains, behavioural and strategic capabilities were viewed as decisive differentiators, with technical expertise necessary but insufficient for success. The findings position the IC-to-FLM transition as a fundamental identity shift toward relational and strategic leadership. The study offers implications for leadership theory in high-risk knowledge-intensive settings and provides actionable guidance for CROs, including strengthening promotion criteria, designing structured onboarding and mentoring, and integrating behavioural assessments into talent identification to reinforce the leadership pipeline.

**KEYWORDS:** Contract Research Organizations, Clinical Research, First-Line Managers, Managerial Transition, Strategic Leadership

### INTRODUCTION

Traditionally, organizations often promote high-performing Individual Contributors (ICs) into managerial positions based primarily on their technical and domain expertise. While technical competence remains valuable, it does not inherently translate into managerial effectiveness.<sup>1,2</sup> The transition to First-Line Manager (FLM) requires a fundamental shift in focus, demanding core people skills such as communication, coaching, conflict resolution, delegation, and motivation to complement technical acumen. Failure to successfully navigate this transition is a high-cost organizational problem, leading to decreased productivity, increased turnover, and compromised project success, thereby derailing both team performance and the individual's long-term career trajectory.<sup>3,4,5,6</sup>

The clinical research industry presents a uniquely complex and demanding environment for such managerial transitions. As a highly regulated sector where adherence to Good Clinical Practice (GCP) protocols, data integrity, and strict timelines are crucial, the stakes are elevated because the ultimate objective is the development of novel therapies that directly impact patient care.<sup>7</sup> Within this context, FLMs must not only ensure compliance with regulatory standards and meet rigorous project deadlines but also nurture highly specialized teams who operate under significant pressure. This role demands a careful balance of technical competence and essential "human side" management skills, such as fostering motivation, managing stress, mitigating risks, and providing guidance.<sup>3,8</sup> For new professionals entering this field, the FLM often serves as the primary touchpoint for navigating operational and emotional challenges.

Contract Research Organizations (CROs) face mounting talent pressures amid robust industry growth of 8.4% CAGR through 2035.<sup>9</sup> Yet new FLMs frequently struggle: 60% receive no training upon transition, 26% feel unprepared, and 20% are rated as poor performers by their subordinates.<sup>3</sup> In addition, 74% of first-time FLM success is driven by behavioural and team responsibility factors rather than technical skills alone.<sup>4</sup> Clinical trial delays are estimated to cost approximately USD 500,000 per day in unrealized



sales, alongside USD 40,000–55,000 per day in direct trial costs.<sup>10</sup> These figures, combined with the impact of turnover on institutional knowledge, underline the strategic importance of effective frontline leadership in clinical research settings.

While general management literature addresses IC-to-manager transitions<sup>11</sup>, there remains a notable paucity of research specifically examining this phenomenon within the clinical research domain. This gap is particularly significant because the industry's regulatory framework, specialized skill requirements, and high-stakes environment likely introduce distinct challenges and success factors that are not fully captured by broader management studies.

To address this gap, the present study explores the IC-to-FLM transition from the perspective of senior leaders in CROs. Senior leaders have direct experience in selecting, coaching, and evaluating new FLMs and are therefore well positioned to identify the critical success factors and essential competencies associated with effective transitions. By focusing on their lived experience, this research provides a strategic, top-down view that offers actionable insights for CROs seeking to identify, prepare, and support their future leadership pipeline.

Human Capital Theory frames relational competencies as investable assets that can yield sustained organizational advantage.<sup>12</sup> Path-Goal Theory highlights the responsibility of FLMs to reduce barriers and provide direction in complex, regulated environments.<sup>13</sup> Leader-Member Exchange (LMX) theory emphasizes the importance of high-quality relationships between leaders and team members for building trust and psychological safety, which are essential for timely error reporting and escalation in clinical trials.<sup>14</sup> Together, these frameworks inform the present inquiry into senior leaders' observations of the factors that differentiate successful and struggling first-time FLMs.

## Research Objective

This study examines the critical competencies and behaviours that enable successful IC-to-FLM transitions in CROs from senior leaders' perspectives, with the aim of informing and strengthening leadership pipelines.

## Research Questions

RQ1: What competencies do senior CRO leaders deem essential for ICs transitioning to FLM roles?

RQ2: What behaviours distinguish thriving versus struggling new FLMs, according to senior CRO leaders?

## METHODOLOGY

This study employs a qualitative approach utilizing thematic analysis. This method was chosen for its flexibility in systematically identifying, analyzing, and reporting patterned meanings (themes) across the data and for explicitly recognizing researcher subjectivity as an active and valuable analytic resource in the co-creation of knowledge.<sup>15</sup>

### *Data collection*

Given the qualitative design and the objective of understanding nuanced perspectives, semi-structured interviews were selected as the primary data collection method. This format allowed an in-depth exploration of participants' experiences, perceptions, and interpretations. Senior leaders provided rich narratives and elaborated on specific examples, which was crucial for generating theoretical insights. The interviews were particularly effective in eliciting tacit knowledge—insights gained through years of experience—that are often essential for understanding critical skills in managerial transitions.

### *Ethical considerations*

This study received retrospective ethical approval from the Research Office at GlobalNxt University (reference EA/120525, dated 12 September 2025). All participants were provided with information about the study's purpose & verbal consent was obtained prior to each interview. All responses were anonymized, securely stored, and handled in line with the best practices for qualitative research in organizational settings.

### *Researcher positionality*

The researcher holds professional experience in clinical research operations and management, with prior exposure to first-line manager development programs. This background facilitated rapport with participants and access to senior leader networks but also required reflexive awareness to mitigate potential confirmation bias toward behavioral competency explanations.



## *Participant selection (sampling)*

Senior leaders were purposively selected if they met the following criteria:

- Held a senior leadership position (e.g., Associate Director, Director, Senior Director, Chief Operating Officer) within a CRO.
- Had at least one year of direct experience in overseeing, mentoring, or evaluating first-line managers who had transitioned from IC roles.

Recruitment was conducted through professional networks and snowball sampling.

## *Interview protocol*

Interviews were conducted virtually via Microsoft Teams or Zoom and lasted approximately 45–60 minutes to allow sufficient depth. At the start of each interview, confidentiality and de-identification procedures were reiterated. No names or specific identifying details were linked to responses. Participants preferred verbal discussion and note-taking over digital recording to maintain a conversational flow. Immediately following each interview, detailed notes and contemporaneous records were expanded into comprehensive written accounts, which served as the raw data for analysis.

## *Sample size*

A total of 10 senior leaders were interviewed. In line with established principles in qualitative research<sup>16,17</sup>, sufficient information power was achieved, with no substantively new insights, codes, or themes emerging from the final interviews. This indicated that the sample size was adequate for a comprehensive and robust analysis.

## *Data analysis*

Interview accounts were imported into ATLAS.ti (version 25.0.1.32924; trial license L-767-126) for data management and coding. Thematic analysis was used to identify common ideas, patterns, and themes in the data.<sup>15</sup> The process involved multiple readings of all accounts, followed by systematic coding of relevant phrases and ideas. Codes were iteratively refined and then grouped into broader themes that directly addressed the research questions concerning critical skills in the IC-to-FLM transition. This analytic process supported a deep understanding of senior leaders' perspectives on what enables first-line managers to succeed in the clinical research industry.

## **RESULTS**

### **Profile of the participants**

A total of 10 senior leaders were interviewed (respondents A to J). This diverse group included 2 Associate Directors, 3 Directors, 4 Senior Directors, and a Chief Operating Officer. Their overall professional experience ranged from 15 to 31 years, with a mean experience of 21.9 years. The participants also possessed substantial experience in managing first-line managers, ranging from 1 to 20 years, with a mean of 11.5 years. Notably, 3 participants reported 20 years of experience in this specific area, representing the most experienced individuals in the sample.

All participants represent leading CROs, overseeing diverse functional teams such as Centralized Monitoring, Safety, Functional Service Provider (FSP), Clinical Operations (Monitoring and project management roles), and Electronic Trial Master File management (eTMF).

Six interlocking themes emerged from the thematic analysis, outlining the critical skills required for a successful transition to FLM role. These themes are summarized, along with the specific concepts that define them and the level of participant endorsement, in

### **Table 1.**

#### **Theme 1: Emotional Intelligence (EI) and Self-Management**

Emotional intelligence and self-management emerged as the most critical foundational theme, strongly endorsed by the majority of senior leaders as essential for the success of first-line managers in clinical research. The core components highlighted included empathy, self-awareness, active listening, and a growth mindset, each contributing significantly to building trust, fostering relationships, and driving team performance.

Empathy was raised repeatedly as a vital but challenging competency. One senior leader noted, "Cannot show empathy, bossing is seen; cannot put themselves in others' shoes," reflecting how a lack of genuine empathy quickly erodes credibility and team cohesion. Leaders pointed out that effective managers must actively strive to understand team members' perspectives and emotional



states, which is essential for creating the psychological safety needed for open communication and risk reporting in highly regulated clinical environments.

A growth mindset stood out as a key differentiator separating successful from struggling FLMS. This orientation involves "seeing feedback as an opportunity for continuous learning" rather than criticism. A participant explained, "Taking feedback positively is a learning attitude," underscoring the importance of receptiveness to feedback and willingness to evolve. This mindset was linked closely with adaptability, resilience, and the ability to navigate the ambiguity and pressure inherent in clinical trial management. Self-awareness and self-drive were described as critical self-management skills enabling new managers to reflect on their limitations and maintain motivation during turbulent situations. One senior leader remarked, "Ability to do self-reflection, rather than thinking about barriers as obstacles," illustrating the active inner work successful managers undertake to grow from setbacks rather than be hindered by them. This aligns with the observed need for unlearning prior individual contributor habits and embracing a new identity as a team leader, which requires conscious effort and humility.

Active listening was emphasized as indispensable, particularly in hybrid or distributed team settings where cues can be missed. Leaders shared that managers who fail to listen carefully to their peers and reports tend to slow down team dynamics and miss early warning signs of issues. One respondent highlighted the value of pairing EI with cognitive understanding: "Understanding basic cognitive science, such as attention and cognitive load, helps time discussions and match expectations to team capacity." This nuanced awareness allows managers to sequence tasks, conversations, and emotional checkpoints more effectively, boosting team performance and minimizing burnout.

Senior leaders also underscored the importance of handling criticism constructively, both in receiving feedback and providing it to others. Managers with strong EI create a culture where feedback is normalized and viewed as an opportunity for growth, rather than as a threat or personal attack. This behavioural norm serves as a foundation for continuous improvement that organizations in clinical research critically need.

These findings mirror the broader literature emphasizing emotional intelligence as foundational for leadership effectiveness and successful managerial transitions.<sup>4,8,18</sup> EI is not merely a 'soft skill' but a strategic capability that underpins other leadership dimensions such as communication, delegation, and conflict resolution. Developing EI requires intentional practice, mentoring, and experiential learning, all of which senior leaders noted as priority areas for new manager development.

In summary, this theme reveals that emotional intelligence and self-management comprise a cluster of interrelated competencies—empathy, self-awareness, active listening, growth mindset, and cognitive self-regulation—that act as the cornerstone for effective leadership transition in the demanding, high-stakes world of clinical research. Organizations seeking to strengthen their leadership pipeline must prioritize cultivating these capabilities through targeted coaching, feedback systems, and reflective learning opportunities.

## Theme 2: Team Building and People Management

As the core function of management, team building and people management were emphasized by several participants as critical areas of focus during the transition. This theme captures the essential shift from relying solely on technical expertise to mastering the administrative and deeply human aspects of leading teams. Senior leaders highlighted the importance of authentic relationship-building and trust as foundational to any effective team dynamic. This begins with consistent, intentional individual engagement; managers must use tools like regular one-on-one meetings not just for monitoring tasks, but to genuinely connect with team members as individuals. One participant reflected, "Understanding more about the employees and their lives, that's helpful to create rapport," highlighting the personal investment required.

Failure to grasp team demands and group dynamics is a frequent stumbling block. Managers are urged to assess and leverage individual strengths for optimal allocation of work, as validated by a participant who stated, "understanding the strength of each person and giving work accordingly." Creating trust involves intentionally avoiding micromanagement, empowering people with autonomy, and fostering an environment where independent thinking is valued. This cultivates psychological safety—a vital condition for employees to take risks and admit mistakes without fear, which is especially important in high-stakes clinical research environments. Conversely, favoritism undermines trust and team cohesion severely.

Effective delegation was consistently noted as a major challenge; one participant observed, "90% are struggling to delegate, they don't trust the work done by their juniors." Delegation, however, is much more than offloading tasks—it is empowerment, giving team members opportunities to grow and lead in small ways. As one leader stressed, "Empowerment is necessary and also having



that oversight that you are available for any challenge." The responsibility of FLMs extends beyond day-to-day task management to include the holistic development and wellness of their team, including mental health.

Role clarity was emphasized as a foundational leadership element, with a participant commenting, "Expectation setting is important in FLM role" to ensure alignment with direct reports. Real-time feedback is a key developmental tool requiring managers to strategically balance positive reinforcement with constructive criticism delivered in relatable, respectful ways. "Giving feedback in a relatable manner is important," was a common refrain, underscoring feedback's dual role in motivation and correction.

The manager also acts as the team's crucial advocate, managing high performers to sustain team balance and representing the collective interests to senior leadership. Adaptability is needed to flex working styles across diverse generations, reflecting the evolving composition of modern clinical research teams. These findings robustly reinforce literature asserting that first-time managers must deliberately cultivate individual relationships and overall team dynamics to succeed.<sup>3,6</sup>

### Theme 3: Communication and Interpersonal Skills

Communication surfaced as a foundational bedrock of effective management, equally endorsed by numerous participants. In the globally distributed and hybrid environments typical of clinical research, FLMs serve as the vital conduit linking senior leadership, peers, and direct reports. Their critical task is to relay strategic messages accurately and without distortion. Discussions like "Regular 121s to understand the team" help maintain these connections and reveal areas where support is required.

Effective communication demands high interpersonal astuteness. Execution frequently falters due to poor delivery and lack of genuine listening; one participant characterized this as managers who "pass judgement without listening," a behavior that severely hinders information flow and team morale.

Navigating organizational politics without compromising personal integrity and team trust was flagged as a nuanced and essential skill. Managers reported difficulties "Navigating office politics without affecting your work ethic, should not affect team and their character." Assertiveness issues, especially in conveying management decisions upward or sideways, often stemmed from "designation fear"—an inhibiting apprehension about speaking up to senior leaders.

Managing cultural differences and sensitivities adds further complexity, with body language and tone becoming critical, especially in virtual settings. Credibility hinges on consistently "walking the talk." Professional responsiveness—including ensuring timely turnaround of emails and requests—is fundamental to maintaining trust. The consistent alignment of words and actions forms the relational foundation upon which team cohesion and effectiveness depend.

The participants' perspectives align well with relational leadership frameworks and echo leadership development literature emphasizing communication as an essential managerial skill.<sup>1,17</sup>

### Theme 4: Leadership and Strategic Skills

This theme encapsulates core capacities such as accountability, decision-making, anticipatory thinking, and the indispensable mindset shift from individual contributor to team-level leader. The transition's success hinges significantly on this fundamental change, as one participant articulated: "Managing at team level, not individual; if no mindset change, adaptability is a challenge." Decision-making was highlighted as problematic for many, afflicted by hesitation, over-reliance on others, or poor prioritization skills. "Confused about taking decision, need to learn making their own decisions," remarked a leader, emphasizing the developmental urgency in building managerial autonomy and confidence. Effective leaders actively gather facts and "run around to get information" to inform choices.

Anticipatory thinking and risk preparedness were described, including what one called a "pre-mortem mindset" focused on foreseeing potential challenges. Cognitive flexibility enables managers to employ and adapt leadership styles such as situational leadership according to context constraints. Participants frequently identified deficits in strategic thinking and business acumen as core reasons for FLM struggles.

Decision-making under uncertainty was described as a delicate area requiring solution orientation and ownership: "Think on their own, be solution oriented, rather than citing challenges." Conflict did not simply constitute problems but opportunities to identify underlying tensions and advance resolutions.

Accountability—taking ownership while providing clear role expectations—underpins a leader's credibility. The environmental uncertainty of clinical research demands leaders with "Ability to handle ambiguity." Business acumen, including prioritization



aligned with organizational goals, further undergird effective leadership. These insights support views that successful leadership development transcends technical mastery to embrace strategic adaptability.<sup>3,19</sup>

## Theme 5: Coaching, Mentoring, and Support Systems

Several participants underscored coaching and mentoring as pivotal enablers of skill growth and confidence building. Access to experienced mentors and continuous coaching were linked with readiness to confront new challenges, with one leader noting the value of “approaching mentors while making some decisions.” Structured mentoring programs, alongside ongoing training, were seen as crucial to facilitate a smooth transition.

Learning from peers and seasoned leaders was encouraged, “Getting mentored by experienced LMs, understanding case studies related to failures and successes,” emerged as a recurrent recommendation. Developmental priorities emerged around cultivating critical thinking, unlearning counterproductive habits, and honing observational learning.

The data likewise illuminated the importance of fostering a growth mindset—not only in new managers but cascading through their teams—to create a culture supportive of continual learning and improvement. These insights reinforce leadership pipeline models that spotlight coaching as a central pillar.<sup>4,11</sup>

## Theme 6: Technical and Analytical Skills

While the study foregrounded people skills, senior leaders acknowledged the enduring significance of domain-specific knowledge and analytical capability. Domain expertise provides a foundation to earn team respect and trust: “Domain specific experience helps to gain respect of the team,” one participant explained.

A problem-solving orientation and strong analytical skills enable managers to make effective decisions. Comments like “Having a good analytical head to make decisions” exemplify this. The ability to comprehend revenue, resourcing, and budgeting emerged as a strategic competency affecting managerial credibility and decision defense.

These findings confirm that emotional intelligence and leadership skills must be integrated with solid technical competence to ensure well-rounded managerial effectiveness.<sup>19</sup>

## THEMATIC INTEGRATION

The findings reveal a coherent capability stack essential for a successful transition from IC to FLM within clinical research organizations.

- **The Foundation: Intrapersonal Mastery and Identity Shift**

At the base lies emotional intelligence and self-management, encompassing core intrapersonal skills such as self-awareness, self-reflection, and a growth mindset. These competencies enable new managers to regulate emotions effectively and build the internal resilience required for high-pressure clinical research environments. Crucially, this level marks a profound identity shift, requiring the manager to “unlearn” prior IC habits—moving from a focus on personal technical output to a focus on team facilitation.

- **The Execution Layer: Interpersonal and Communication Skills**

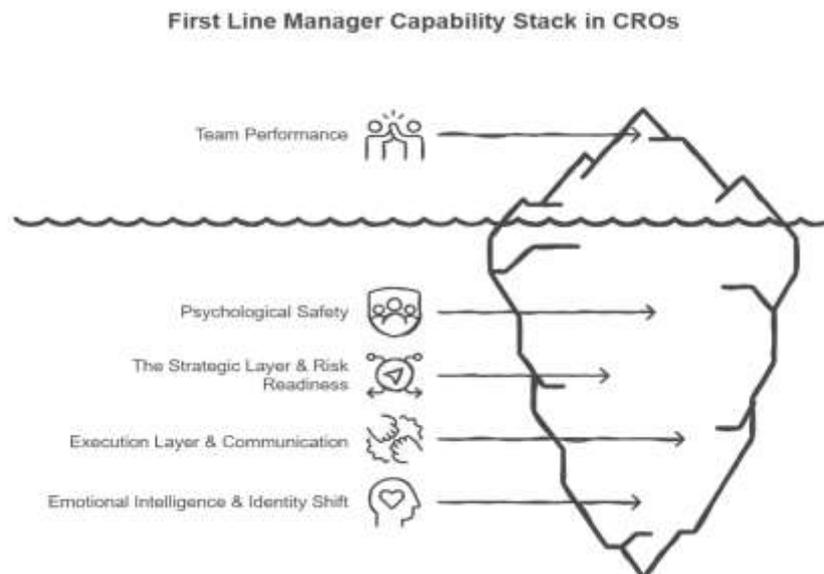
Building on this foundation are the interpersonal skills representing the critical execution layer. This involves authentic relationship-building, effective delegation, and overcoming “designation fear” to ensure strategic messages are relayed accurately without distortion. Culturally attuned communication and active listening foster psychological safety—an environment where team members feel safe to report errors or take risks without fear of retribution.

- **The Strategic Layer: Leadership Capabilities**

The next layer comprises strategic leadership capabilities, including anticipatory risk readiness, informed decision-making, and business acumen. These enable managers to navigate uncertainty by adopting a “pre-mortem mindset” to foresee potential challenges before they impact the team. This layer ensures managers move beyond task-level thinking to align their teams with organizational priorities.

- **The Integrative Force: Psychological Safety and Organizational Enablers**

Overarching these layers are organizational enablers such as structured coaching and mentoring, which scaffold skill growth and confidence. Central to this entire stack is psychological safety, which functions as the integrative and mediating force. It establishes the trust climate crucial for thriving in a regulated industry, ensuring that both intrapersonal and interpersonal competencies translate into higher team performance and transparent communication of risks.



**Figure 1.** The FLM Capability Iceberg. This model illustrates the hierarchical progression of competencies required for managerial success in CROs. Visible Team Performance is sustained by foundational Intrapersonal Mastery (Identity Shift and Emotional Intelligence), an Execution Layer of interpersonal communication, and a Strategic Layer of risk readiness. Psychological Safety acts as the mediating force at the waterline, enabling these subsurface assets to translate into organizational value.

**Data Triangulation**

To enhance confidence in these findings, data triangulation was applied by integrating thematic codes with direct participant quotations. This convergence validated core leadership competencies including accountability, ownership, communication clarity, active listening, emotional intelligence, empathy, and a growth mindset. Concurrently, challenges such as micromanagement, defensiveness in receiving feedback, and delegation difficulties surfaced vividly through participant narratives, affirming their prevalence.

Themes displayed nuanced variations enriching understanding, such as the psychological adjustment involved in the mindset shift and the crucial role of mentoring and coaching in supporting managerial capability development.

Organizational supports—specifically ongoing training and mentoring programs—were consistently recognized as essential systemic mechanisms that complement individual efforts and facilitate smooth managerial transitions.

Together, these triangulated insights confirm that the transition from IC to FLM is a complex, multifaceted process influenced by the dynamic interplay of individual behaviors and organizational context. This integrated understanding offers senior leaders actionable guidance to strategically invest in leadership development, promote open communication and continuous feedback cultures, and establish robust mentoring systems to strengthen managerial pipelines in clinical research organizations.

**DISCUSSION**

The transition from an IC to a FLM is a profound professional transformation requiring a fundamental shift in mindset, identity, and relational skills rather than a reliance on technical competence alone<sup>1,12,19</sup>. This finding resonates with Human Capital Theory<sup>12</sup>, which frames behavioral capabilities as investable assets critical for organizational value. Senior leaders in this study observe that excelling as an IC does not guarantee managerial success. Instead, the transition requires intrapersonal mastery, where the manager must "unlearn" prior habits to embrace a relational leadership identity. By developing these internal capabilities—such as self-awareness, self-reflection, and a growth mindset—CROs create strategic competitive advantages consistent with the Resource-Based View (RBV)<sup>20</sup>.



Two key leadership theories interpret the behavioral changes observed: Path-Goal Theory (PGT) and Leader-Member Exchange (LMX) Theory<sup>13,21</sup>. PGT suggests that effective leaders clarify paths to goals by adapting their styles to situational demands. Our findings—specifically the need for a "pre-mortem mindset" and anticipatory risk readiness—reflect the FLM's responsibility to remove obstacles in a high-stakes clinical environment. Struggling managers often remain stuck in a task-focused style, failing to adopt the participative approaches necessitated by PGT's style adaptability principle.

Building on this, LMX theory emphasizes that leadership effectiveness depends on high-quality, trusting relationships. Foundational intrapersonal skills enable the interpersonal execution required to build these bonds. Mastering the "human side" of management—including empathy and active listening—allows FLMs to overcome "designation fear," ensuring strategic messages reach senior leadership accurately. This high-trust dynamic fosters psychological safety, an absolute requirement for the transparent reporting of errors and risks essential to trial integrity and patient safety.

The capability framework emerging from this study integrates behavioral, strategic, and technical dimensions. Success depends not on authority alone but on influence and collective empowerment. This study extends the understanding of managerial transitions into the underexplored, highly regulated context of CROs. By drawing on senior leaders' top-down perspectives, the research provides a holistic understanding of the competencies required to drive resilience and competitive advantage in clinical research.

## CONCLUSION

This study addresses a significant gap in management literature by providing a strategic, senior leadership perspective on managerial transitions within the highly regulated CRO sector within the clinical research industry. The findings offer a comprehensive capability stack framework that bridges the gap between technical expertise and relational leadership. By framing the transition as a profound professional transformation rather than a mere promotion, the research highlights the necessity of a fundamental shift in both mindset and identity.

The research establishes that securing a high-performing cohort of FLMs is essential to the CRO service delivery model and the maintenance of competitive advantage. Success in this transition depends on a clear hierarchical progression: starting with intrapersonal mastery, which requires the conscious "unlearning" of individual contributor habits, and moving toward interpersonal execution to build high-quality Leader-Member Exchange (LMX) bonds. These competencies collectively foster psychological safety, which functions as the integrative force required for transparent risk reporting—a non-negotiable ethical and business imperative in clinical research. Ultimately, strategic investments in the frontline leadership pipeline are vital for ensuring long-term organizational resilience and safeguarding trial integrity within the global clinical research ecosystem.

## Practical Recommendations

Based on the study's findings, CROs can strengthen their leadership pipelines by implementing targeted practices categorized by their level of influence on the manager's transition:

### 1. Foundational & Individual Focus: Cultivating Intrapersonal Mastery

- **Redefine Promotion and Selection Criteria:** Organizations should recognize that technical excellence alone is an insufficient predictor of managerial success. Selection processes must prioritize intrapersonal mastery, evaluating candidates for emotional intelligence, self-reflection, and a growth mindset alongside domain expertise.
- **Address the Identity Shift and "Unlearning":** Onboarding programs should explicitly facilitate the psychological transition from "doing" to "leading". This includes helping new managers unlearn individual contributor habits and embrace a new identity focused on team-level facilitation rather than personal technical output.

### 2. Relational & Skill Focus: Enhancing Interpersonal Execution

- **Mitigate "Designation Fear":** CROs should provide targeted communication workshops to help FLMs overcome apprehensions about upward management. Training should focus on assertive communication and the ability to relay strategic messages across the organization without distortion.
- **Foster Psychological Safety through Relational Leadership:** Managers should be trained in relational leadership techniques, such as active listening and empathetic engagement, to establish the high-trust bonds described in Leader-Member Exchange (LMX) theory. This climate is essential for transparent error reporting in regulated environments.



### 3. Strategic & Systemic Focus: Building Organizational Resilience

- **Establish Formal Mentoring and Coaching Systems:** Pair new FLMs with seasoned leaders to provide ongoing guidance and confidence-building. Structured mentoring accelerates the learning curve and provides a safe space for managers to discuss challenges like delegation and conflict resolution.
- **Implement "Pre-Mortem" and Risk-Based Simulations:** To cultivate anticipatory risk readiness, organizations should use workshops that simulate high-stakes decision-making under uncertainty. These simulations help managers adopt the "pre-mortem mindset" required to protect trial integrity and timelines.
- **Integrate Continuous Feedback Loops:** Encourage a culture where senior leaders provide real-time, relatable feedback to new managers. This reinforces accountability and provides the necessary scaffolding for sustained behavioral growth.

### LIMITATIONS AND FUTURE RESEARCH

This study has several limitations that warrant consideration. Primarily, it relies on a top-down perspective from senior managers, which excludes direct input from FLMs and their teams, limiting ground-level insights into the transition experience. Additionally, the qualitative design with a limited sample size focused primarily on CROs restricts statistical generalizability across broader settings. The retrospective nature of the data also introduces the potential for memory bias.

Future research should incorporate perspectives from FLMs themselves and their direct reports to develop a more comprehensive, multi-stakeholder understanding of the transition process. Longitudinal studies are also necessary to observe how new managers evolve over time and to evaluate the sustained impact of development programs. Extending research to sponsor organizations within the clinical research industry may provide valuable comparative insights into leadership requirements across the clinical trial ecosystem.

Despite these limitations, this study offers a robust conceptual framework that meaningfully contributes to leadership development literature and provides actionable guidance for organizations supporting managerial transitions in complex, high-pressure environments.

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**Table 1: Summary of Critical Competency Themes, Defining Concepts, and Respondent Endorsement (N=10)**

| Theme                                       | Defining Concepts                                                                                                                                                                                                                                                                                                                     | Respondents               |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| 1. Emotional Intelligence & Self-Management | Empathy; Flexibility; Growth Mindset; Non-judgemental attitude; Positive mindset; Self-awareness; Self-drive; Self-motivation                                                                                                                                                                                                         | A, B, C, D, F, G, H, I, J |
| 2. Team Building & People Management        | Appreciation and recognition; Collaboration; Conflict management; Effective Delegation; Empowering team members; Team engagement; Flair for people management; Knowing your team; Motivation at the team level; Open to feedback and two-way conversation; Peer interaction; Trust & Rapport; Understanding individual team strengths | A, B, F, G, H, I, J       |
| 3. Communication & Interpersonal Skills     | Active Listening; Communication clarity; Documentation of challenges; Interpersonal astuteness; Managing escalations; Navigating organizational politics; Networking; Positive feedback; Problem-solving orientation; Regular catch-ups; Tolerance to ambiguity                                                                       | A, B, D, E, F, G, H, I, J |
| 4. Leadership & Strategic Skills            | Accountability; Assertiveness; Confidence; Decision-making; Learning attitude and Relational Leadership; Mindset shift; Ownership; Prioritization; Situational leadership; Stakeholder management; Strategic thinking; Upward management; "Walk the talk"; Tolerance for ambiguity; Pre-mortem mindset.                               | A, B, C, D, E, F, H, I, J |
| 5. Coaching, Mentoring & Support Systems    | Capability building; Coaching and mentoring; Grooming team members; Power of observation                                                                                                                                                                                                                                              | A, C, D, E, G, H, I, J    |
| 6. Technical & Analytical Skills            | Domain-specific technical knowledge; Understanding role demands                                                                                                                                                                                                                                                                       | A, B, F                   |

*Cite this Article: Agrawal, V., Bhandar, M. (2026). Building First-Line Leadership in Contract Research Organizations: Senior Leaders' Perspectives on Critical Transition Competencies. International Journal of Current Science Research and Review, 9(1), pp. 426-435. DOI: <https://doi.org/10.47191/ijcsrr/V9-i1-56>*