

Paper PD09

Which Side of the Fence Are You on? A Head of Statistical Programming's Perspectives Working for Sponsor and CRO

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Overview



My Story

What to Expect Working for Sponsor and CRO

What is Working, What Can be Better!

Challenges of Navigating the Sponsor-CRO Relationship

Best Approaches to Build a Healthy, Collaborative, Effective and Rewarding Partnership

Conclusion

My Story



2001 - 2018, 2021-

2019 - 2021

Career Development Overview

2001 - 2018

- ❑ **Sponsor - Pharma & Biotech**
- ❑ Varied TAs
- ❑ Varied SP R&Rs
- ❑ People & project management
- ❑ Head of Oncology standard process & innovations
- ❑ Head of SP & Data Analytics
- ❑ **Partner with most global CROs**



2019 - 2021

- ❑ **CRO - leadership** R&Rs for global multidisciplinary team & projects
- ❑ Head standards & innovations team
- ❑ Cross-functional standard E2E process committee
- ❑ **Manage multiple high-profile sponsors' projects bid defense, accounts mgmt & governance**



2021 -

- ❑ **Sponsor - Biotech**
- ❑ Set up infrastructure and standard prog process from scratch
- ❑ NDA submissions prep work
- ❑ Legacy studies conversion
- ❑ Global studies standardization
- ❑ Cross-functional standard E2E process committee
- ❑ **Partner with CROs**

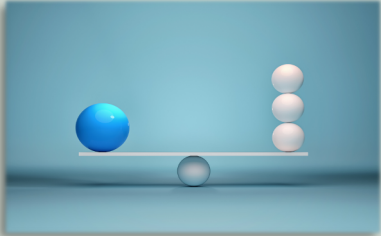
What to Expect Working for Sponsor and CRO

- ❑ Roles and Responsibilities
- ❑ Differences and Similarities
- ❑ What to expect, how to adjust /adapt
- ❑ Pros and Cons



	Sponsor	CRO
Bid Defense Governance	Leadership level	Leadership level
SP Capacity 	❑ FTE, smaller team, on-site (remote pandemic) ❑ Direct interact with entire study team, provide perspectives and inputs toward study designs ❑ Direct communications with regulatory agencies ❑ Focus on specific TAs or projects	❑ FSP, Niche Provider, specific SMEs, entire or segment of projects ❑ Larger team, remote & tele-comm ❑ Sponsors project, time & materials, per unit/unit-rate based ❑ Competing multiple sponsors and projects

	Sponsor	CRO
TAs/Projects Opportunities 	❑ Big Pharma vs Biotech: vast vs limited TAs & pipelines ❑ Big pictures, in-depth knowledge of clinical studies E2E process, scopes, timelines and end products	❑ Broader sponsors, TAs and projects exposure ❑ Small picture, limited visibility to the full project, focus on getting/working on rewarded sponsors/projects per work scopes, timelines & budgeted resources
Career Development	❑ Steady career development ❑ More conferences/training opportunities ❑ Value-added career growth	❑ More variety of projects, move on to management role faster ❑ In-house trainings, conferences & external training only for speakers

	Sponsor	CRO
Work-Life Balance 	☐ Promote work-life balance, “It’s a marathon not a sprint” ☐ Curve through the life cycle of projects ☐ Big pictures of projects deliverables	☐ Multiple sponsors, projects, global programming teams with competing timelines, burn out easily ☐ Set your limits, or easier to get buried under if boundaries are not well defined
Job Security	☐ One drug/TA company ☐ Big Pharma job replaced by outsourcing model ☐ Biotech acquisitions	☐ Multiple sponsors and projects, if one project gets terminated, can easily move on to other sponsors or projects ☐ At the mercy of clients & new projects

What is Working, What Can be Better!

SPONSOR

- ✓ Set up clear R&Rs, expectations, requirements at the bidding and project KO meeting (i.e., vendor delivery requirements)
- ✓ Set CROs up for success, not for failure
- ✓ Timely and constructive communications and feedbacks for improvements
- ✓ Standard issue tracking, escalation and decisions making process

CRO

- ✓ Set up standard timelines, quality review, delivery process, and effective communications channels
- ✓ It's OK to say No! and provide alternative solutions
- ✓ Be transparent for the potential issues and risks that might negatively impact the overall quality and delivery timeline
- ✓ Be flexible and willing to make timely changes and improvements

Challenges of Navigating the Sponsor-CRO Relationship

- ❑ **Oversell during the Bid Defense:** “Don't promise anything you can't deliver.”
- ❑ **R&Rs and Expectations:** define, confirm and document in detail early
- ❑ **Poor Communications:** be clear about what, when and how to
- ❑ **Poor Management by Sponsor:** Hands-off vs Micromanagement
- ❑ **Lack of Transparency**
- ❑ **Lack of Information Sharing**
- ❑ **Lack of Common Platform**



Best Approaches to Build a Healthy, Collaborative, Effective and Rewarding Partnership

- ❑ Well defined R&Rs, expectations, goals, standard process and follow thru
- ❑ Mutual respect, treat as partner and teammate
- ❑ Improve communications & collaboration to drive productivity, information sharing, be transparent, frequent virtual meetings vs face-to-face visits
- ❑ Assume Positive Intent!
- ❑ Nothing Personal, It's Strictly Business!



Best Approaches to Build a Healthy, Collaborative, Effective and Rewarding Partnership

- ❑ Effective governance, oversight and commitments at both sides
- ❑ SMEs at both sides
- ❑ Issues escalation and decision-making process
- ❑ How do both sides benefit!
- ❑ Motivate and reward, don't forget to praise generously



Conclusion

❑ What type of fences are you building between your company/department and your sponsor/CRO partner?

(A) Transparent, see the same big pictures (goals), with defined boundaries yet easy to navigate thru.

(B) You are on your own side of fence. What next?



Thank You

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