Risk Mitigation Within a Contract Research Organization

Dr. Justin Binik-Thomas, DBA, CPhT Emeritus

DeVoe School of Business
Indiana Wesleyan University, USA

Justin.Binik-Thomas@myemail.indwes.edu
https://www.linkedin.com/in/binikthomas/

Introduction

The study contemplated improving days and dollars outstanding within the contract research organization (CRO) industry. The partner organization suffered several million dollars per quarter in unrecovered costs. The scholar-practitioner was challenged to research and identify trends and techniques across various industries that could be directly applied or adapted to the stated problem. Two driving research questions were the focus of the study:

- How can the organization reduce the days sales outstanding metric to better position the partner organization to mitigate the financial risk of work performed more efficiently before obtaining written approval?
- What can the partner organization do to proactively identify changes in contractual scope, increasing or decreasing, without compromising the project flow or the delegated authority?

Background

Industry contracts, including the partner organization, contain standard legal language for predictable changes, such as client requests. The CRO industry also has some unusual challenges, including changes from regulatory agencies, which may result in legal prohibition to stop work if impacting patient safety (Cowell, 2012; Hack & Sackner, 2017). These restrictions apply even if the organization has not yet paid. In some cases, the organization is bound to protect patient safety without an existing contract to perform the task. In the contract review period, the partner organization has also historically dealt with inappropriate and aggressive government intrusion blamed on pandemics, endemics, and wars (Ghodoosi 2022). Consequently, most CROs have relied on utilizing an earned value management tool and change in scope authorization forms to identify and obtain written approvals for delegated work proactively.

The partner organization requested the study incorporate a root cause analysis with internal stakeholders to ensure all parties understood the problem areas. At issue in the consulting engagements were factors that combine in complex and unpredictable ways, creating risks that can be difficult to anticipate and control" (VelocityEHS, 2020, para. 2). Refer to Figure 1. The root cause analysis indicated the need for the organization to:

1. Improve forecasting to proactively gain approvals for changes to units.
2. Gauge if unit changes also impacted effort.
3. Report any novel client requests.

Early completion of the preliminary analysis allowed for a more streamlined literature review of the best practices across the industry (Binik-Thomas, 2022). The literature review identified several gaps:

- *Pre-payment Discount.* The existing contracts contain a late payment penalty clause, one of the few one-way clauses within the agreements. However small, adding a pre-payment discount would restore the document's bilateral nature and may result in quicker payments, particularly with clients with use-it-or-lose-it budgeting constraints (Zhao & Huchzermeier, 2019).
- *Volume Rebate.* Similar to loyalty programs at clothing and grocery stores, a volume rebate returns a percentage of funds received in one year as a credit to invoices against new work the following year. The partner organization has flexibility on how restrictions on percentage earned and duration credits are applicable (Zhao & Huchzermeier, 2019).
- *Alternate Payment Methods.* Generally, company leadership do not mind the origin of payments, provided the account is in good standing and that payments comply with applicable laws and regulations. The CRO industry may benefit by allowing additional payment methods, such as credit cards or payments from different checking accounts or affiliates (Baker, 2016, 2017).

Company applications included:

- *Consistent Finance Packages.* A company working without written permission has significant financial and legal risks. Proactive financial communications, such as units completed and units remaining, may mitigate the risk since changes shouldn't surprise. More effective analysis may also present trend lines for longer-term planning (Baron, 2010).
- *Clear Delegated Authority.* The clear delegation of authority within the organization is essential because it is imperative to maintain constructive relationships with internal and external customers. Providing transparency in the process and presentation for the reviewers on both sides of the deal yields a quicker turnaround. If needed, it helps all parties work toward a binding agreement for billing, revenue, and headcount. No process is foolproof or firm, but authority bands are required to ensure all parties work harmoniously towards a common goal of clear contracting and on-time and on-budget work (Gladstone & Brown, 2022).
- *Signed Preapproval.* Items outside the contract's scope need written documentation to clearly understand which party is performing actions and how much the efforts will cost. In the CRO industry, regulatory agencies require this step even if there is no financial change in position (Baker, 2017).

Recap

A loose application of problem-based learning is essential with the vital components of a defined problem, a risk analysis, proposal, implementation, and feedback loops (Hmelo-Silver & Eberbach, 2011). Identifying any known limitations within the industry (e.g., patient safety in clinical research) is necessary to assure a proactive off-ramp, such as a trigger for an automatic termination clause.

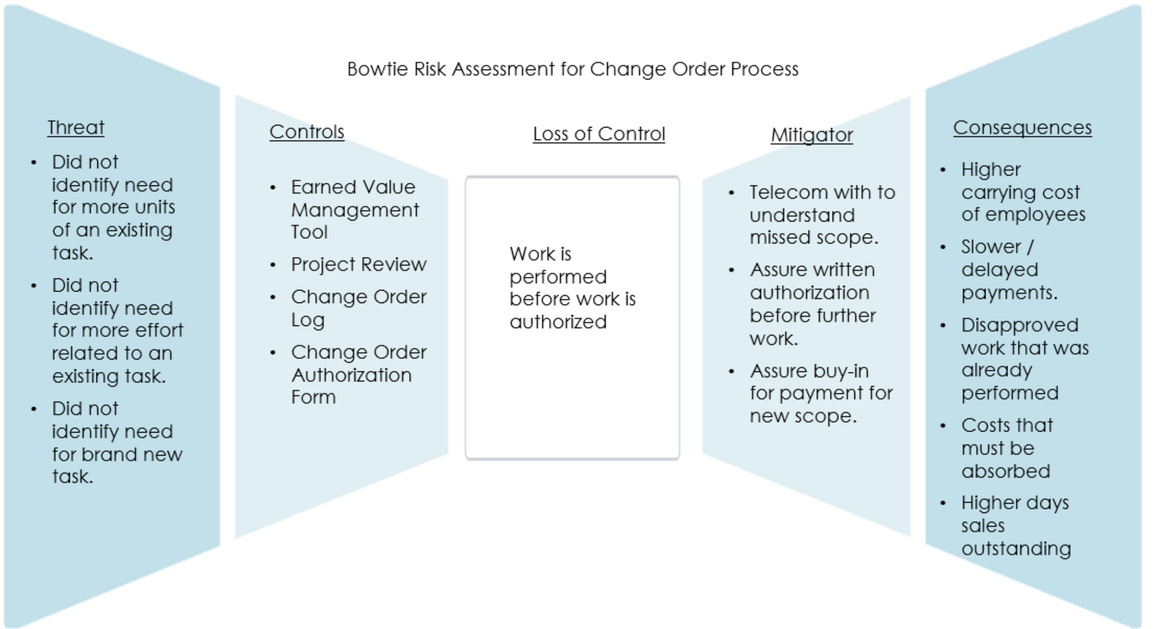
At the start of the project there were 116 days sales outstanding which was reduced to 41 days outstanding in the last validated quarter; this number is well below the board directive of 60 days (Binik-Thomas, 2022). The partner organization deemed the study successful and presented key findings and recommendations at various sales and board meetings. These findings were well received and noted to be above expectations and ahead of industry norms. The partner organization is now in a better position to reduce days sales outstanding and dollars outstanding, which fully supports the partner organization's request. Further, the partner organization can claim revenue on preapprovals while their peer group (competitors) must defer claiming revenue until contractual signature, value-added service to the investors is realized.

Conclusion

Several actions in other industries apply to clinical research: pre-payment discounts, alternate payment methods, and granting volume rebates. Further, some of the approaches within this industry apply to other sectors, including revenue-driving preapprovals, clear delegated authority, and consistent financial reports.

Figure 1

Bowtie Risk Assessment for Change Order Process



Note. The above figure resulted from the bowtie analysis (Binik-Thomas, 2022, Figure 1).

References

Baker, G. (2016). Keeping the lifeblood flowing. *NZ Business*, *30*(10), 22–28.

Baker, G. (2017). A beginner's guide to cash flow management. *NZ Business*, *31*(10), 20–24.

Binik-Thomas, J. (2022). *Risk mitigation within a contract research organization: Dollars and days outstanding* [Unpublished applied doctoral project]. DeVoe School of Business, Indiana Wesleyan University.

Cowell, T. (2012). Boilerplate provisions in clinical trial agreements. *Journal of Clinical Research Best Practices, 8*(6). 1–7. https://www.magiworld.org/resources/journal/1198_Boilerplate.pdf

Ghodoosi, F. (2022). Contracting risks. *University of Illinois Law Review, 2022*(2), 805–859.

Gladstone, M., & Brown, S. (2022). Soft skills in a hard world: Why emergency management and business continuity leaders must update their professional toolbox. *Journal of Business Continuity & Emergency Planning, 15*(3), 225–236.

Hack, V., & Sackner, D. (2017). The changing role of the CRO: Impact on project management. *Applied Clinical Trials*, *26*(6), 43–45.

Hmelo-Silver, C. E., & Eberbach, C. (2011). Learning theories and problem-based learning. In S. Bridges, C. McGrath, & T. Whitehill (Eds.), *Problem-based learning in clinical education* (Vol. 8, pp. 3–7). Springer. https://link.springer.com/chapter/10.1007/978-94-007-2515-7_1

VelocityEHS. (2020, April 7). *Bowtie analysis: Connecting the dots between risks, root causes, and impacts*. https://www.ehs.com/2020/04/bowtie-analysis-connecting-the-dots-between-risks-root-causes-and-impacts/

Zhao, L., & Huchzermeier, A. (2019). Managing financial distress with advance payment discount and purchase order financing. *Omega*, *88*, 77–90. https://doi.org/10.1016/j.omega.2018.10.019