

An Alternative Approach to CRO Contracting: The Shared Performance Contract, Balancing Cost, Transparency, and Risk.

Authors:  
Roger Joby  
David Webber  
Simon Taylor

J R E D <sup>TM</sup>



**Contract Research Organisations (CROs) are well-established in clinical research, generating significant revenues (estimated \$59.8 billion in 2023) (1) by managing and executing clinical trials for pharmaceutical and biotech companies. Despite the key role CROs play, many sponsors remain dissatisfied due to frequent cost overruns and change orders, which disrupt budgets and timelines.**

This in turn erodes the trust between Sponsors and CROs.

We believe this dissatisfaction is driven at least in part, by the structure of clinical research contracts, which have historically struggled to balance cost predictability, schedule overruns, risk allocation, and financial transparency.

## The evolution of CRO contracting models

The Pharmaceutical industry has employed several contract structures since outsourcing came to prominence in the mid-1980s, each with distinct advantages and limitations:

### Time and materials

Sponsors reimburse CROs for hours worked, and costs incurred. This ensures CROs are fairly compensated for their activities but creates uncertainty for sponsors, who perceive this as a 'blank cheque.' Without strong controls Costs can escalate, leading to budget overruns.

### Fixed price contracts

These contracts provide sponsors with budget certainty by setting a predetermined cost for the entire study or major components. This approach however transfers all financial risk to the CRO, which can lead to quality compromises, excessive change orders to recover unexpected costs or inflated estimates to account for uncertainty.

### Fixed unit pricing

The price is set for specific units of work (e.g., site monitoring visits, database management etc). This allows for simpler budget forecasting and streamlines change order management as the activities are captured in discrete units of work with a pre-agreed cost. However, if the unit prices are inaccurate, the sponsor may have no visibility into actual costs incurred. Furthermore, there is a potential for the CROs to err on the high side with their unit estimates to provide a buffer against unexpected changes.

### Competitive Bidding and Optimistic Proposals

Competitive bidding is currently the standard industry approach and involves sponsors requesting proposals from multiple CROs. This often results in proposals with best case scenario timelines where risks are underestimated or omitted to keep the costs down. As a result, projects are at risk of incurring unexpected costs, leading to multiple change orders and strained sponsor-CRO relationships.

## Risk-sharing, transparency, and performance-based incentives

It is possible to adopt a more transparent and balanced contract, one that ensures fair compensation while fostering trust and efficiency and most importantly is beneficial for both Sponsors and CROs. The optimal solution would perhaps consist of several key elements:

### Joint risk assessment and costed contingency plan

Before finalising the contract, the Sponsor and CRO conducts a joint risk assessment to identify potential pitfalls and challenges. A costed contingency plan would be built into the budget, ensuring that the most likely foreseeable risks (e.g., recruitment delays, regulatory changes) and contingencies are accounted for upfront rather than leading to requests to change the study budget. This promotes open and transparent discussions about risks and minimises the potential for CROs to submit unrealistically low bids.

### Transparent budget management

Sponsors pay for actual hours worked rather than fixed units. CROs provide detailed cost breakdowns, with detailed reports of actual effort and expenditures. This removes the potential for hidden/ambiguous costs and misaligned incentives, fostering a more collaborative relationship. The CROs profit margin is secured as it is built into the agreed charge out rates, and CRO cash flow issues caused by milestone payments are removed by paying for all work as it is performed on an ongoing basis. Greater transparency to the effort required allows for refinement of future budgets and greater accuracy over time in subsequent studies. This form of 'open book accounting' is used effectively in large, complex construction projects and is promoted by the UK Government procurement policies. (2)

### Deliverable-based units

Payments are based on effort; however they are tied to deliverables (e.g., 'Sites initiated') rather than activities (e.g., 'site monitoring'). Understanding the relationship between the work delivered and the amount of budget spent provides the opportunity to evaluate efficiency and promote accountability by focusing on delivered progress.

### Project performance tracking

Project performance is tracked throughout the project by comparing budgeted costs to actual costs and progress. This provides an early indication as to approaching cost overruns or inefficiencies where budget spent does not equate to progress made creating visible trends allowing for proactive course corrections which are discussed and jointly agreed by both parties. This enables both sponsors and CROs to make data-driven decisions rather than relying on rigid contract structures.

### Pain/gain sharing



In this model, both the sponsor and CRO compare actual costs to the initial budget upon project completion. When costs are lower than expected (cost savings), both parties share in the financial gain. When costs exceed the budget (overspending), both parties share the financial burden. This introduces the potential for mutual accountability and introduces an incentive for both sides to manage the study efficiently.

## Conclusion

The clinical research industry requires contract models that foster transparency, efficiency, and trust between sponsors and CROs. By implementing joint risk assessments with costed contingency plans, open-book accounting, deliverable-based units, effective progress measurement, and a pain/gain sharing model, both parties can align their interests and share responsibility for project outcomes.

We believe this approach not only reduces mistrust but also drives efficiency and financial discipline, leading to better execution of clinical trials and ultimately accelerating the delivery of new therapies to patients.

## References

1. *Global Market Insights "Contract Research Organisation (CRO) Market – By Service Type, By Therapeutic Area, By End Use, Global Forecast (2024 – 2032)"* - [gminsights.com](https://www.gminsights.com)
2. *Procurement Policy Note, "Open Book Contract Management" February 2025* - [www.gov.uk](https://www.gov.uk)

Acknowledgements: The authors wish to thank the numerous industry experts who have provided their thoughtful insights into the preparation of this paper.

## About the Authors:

Roger Joby is Director of the CURED Framework and Visiting Research Fellow at Liverpool John Moores University and is particularly interested in reducing relational risk in outsourced projects. Dave Webber is a member of the Pharmaceutical Contract Management group and a strong proponent of developing collaborative partnerships between Sponsors and Service Providers. Simon Taylor is Co-founder and Executive Director of th3rdcurve who specialise in project controls and tools to help teams adapt and keep them heading in the right direction.

Profiles of the CURED team can be found on the website [About Us | CURED](#)