



# Managing Outsourced Development:

## DESIGNING A PERFORMING PROCESS

Waife & Associates Inc.

**W**ith the rise of mega-CROs, and the widespread willingness of large pharma to outsource clinical development to them, is there anything left for a sponsor's clinical development group to do? Indeed yes. More than ever, there are hyper-critical functions that sponsors must execute effectively to produce success in clinical development. This can be summarized as implementing a performing process for managing outsourced development.

It is a truism that pharma companies "hate" their CROs, while at the same time pharma companies are using those same service providers more and more. The current fashion for "strategic" relationships has not ameliorated this at the operational level, although perhaps at the executive level. Much like what happened with software providers, where the failure of clinical development applications could often be traced to poor implementation by the sponsor customer, so too can frustrations with CRO performance be traced to suboptimal vendor management by sponsors. Both sponsors and their providers can benefit greatly from improved provider management, which can create a positive cycle of trust, high performance, and higher value.

### Increasing the Management

Those with long outsourcing experience understand that it takes robust internal project management to ensure high provider performance. This is also true when offshoring functions. Too frequently, however, this increased oversight is not budgeted for. Most

Contributed by



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importantly, as similar as the functions of clinical operations are, whether done in-house or by a provider, the process for managing, contracting, measuring, and ensuring high performance must be substantially different in the two scenarios.

Again, too frequently, new processes, and the subsequent redefinition of roles and responsibilities, along with concomitant training, are not designed and implemented.

### Outsourcing the Conflicts

Moreover, if outsourcing was chosen in order to eliminate interdepartmental conflict, it is likely that the conflict will continue when the services are outsourced; essentially the conflict is simply outsourced along with the function. If clinical and data management mistrust each other when both are in-house, this mistrust is likely to continue if outsourcing one or the other is all that is done to try to fix it.

Without open recognition of existing issues with governance, interpersonal conflict, differing philosophies (about data cleaning, about the purpose of monitoring, about the role of science, etc.), these factors — all creators of suboptimal performance — will persist and likely be exacerbated in an outsourced operational model.

How would we recognize a performing process? There are a number of indicators:

- » Fewer agenda items about conflict or performance at the Joint Operations Committee meetings
- » Lower staff turnover on the service

provider team, and seamless execution when it does happen

- » Full transparency for both sponsor and provider on the status of all trial elements (from protocol changes to deliverable delays) and on the reasons for these changes
- » Fewer amendments, fewer change orders
- » Both sponsor and vendor feeling safe to tell each other the truth
- » Ready knowledge of which vital few metrics are important, and where "we" (sponsor and provider) stand on those metrics
- » Easier contracting and faster study startup because of the trust and transparency built — not from a "strategic" handshake, but from demonstrable high performance.

### Respecting the Profession

We can't successfully outsource what we don't respect or don't understand. The long-term danger in prolonged outsourcing is that the fundamental and critical knowledge of operationalizing a protocol will have disappeared from sponsor staff. We must be vigilant to prevent this. Active and fully funded vendor management is one step in preserving operational understanding in the midst of scientific inquiry. This ensures an environment that creates the opportunity for innovation in high-performing processes and development excellence. **PV**

**Waife & Associates Inc.** is a change management consultancy dedicated to the clinical research process.  
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# Finding efficiency in clinical research



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