



Phuse 2018

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MANAGING THE IMPOSSIBLE: CRO OVERSIGHT

Detlef Nehrdich
Senior Associate
Waife & Associates, Inc.



Agenda

- **Introduction**
- **Issues**
- **Ideas for Solutions**
- **Conclusion**



Introduction





Motivation

Sponsor can transfer responsibilities but retain responsibility for the work completed by a CRO

FDA Warning Letter:

"As sponsor of Studies ... conducted under Investigational New Drug Application ..., you were responsible for ensuring that these studies were adequately monitored for compliance with regulatory requirements..."

EMA Presentation:

"No clear communication lines between investigator, CROs and sponsor, lack of communication; audits insufficient, no documentation which tasks are delegated from the sponsor to the CRO (the only documentation is an e- mail: '...trial is out-sourced to.....')"



Consequence

Inappropriate CRO oversight is not only an inconvenience for the people involved but it also bears a considerable regulatory risk.

THE WALL STREET JOURNAL. | BUSINESS

ASIAN BUSINESS NEWS

New Outsourcing Frontier in India: Monitoring Drug Safety

Business Is Booming as Regulators Require Closer Tracking of Side Effects

\$12 FOR 12 WEEKS

Top Story

Outsourcing drug safety checks to India concerns experts

It's Time To Stop Outsourcing Pharma R&D To India

DISPATCHES FROM DIA

Pfizer offers update on risk-sharing deals with Icon, Parexel

By Zachary Brenner 20 Jun 2014

CROs moving away from strategic partnerships? Survey investigates



The Issues



Waife & Associates' Perspective

- We see patterns among our clients
- We share some issues seen and solutions working with our clients
- We use the term “Vendor Oversight Management” (VOM) as this also includes technology providers like IVRS, Labs, EDC/Data Warehousing/eTMF vendors... And the issues aren't any different



Frequent Dilemmas (1)

- Rapid pipeline growth vs. disappointing CRO performance and insufficient internal staff size or experience
- Desire to increase perception and fact of professional vs. service contribution to, while internal resources are constrained and under-prepared
- Management believes that “one size fits all”
- Internal staff is not skilled and not trained to manage vendors
- Internal study team collaboration is sub-optimal
- Definition of internal roles in an outsourcing environment is lacking





Frequent Dilemmas (2)

- Handling multiple outsourcing approaches in parallel
- Risk of administrative overkill of third party contracts
- Contract issues:
 - Very specific about “Bonus”
 - Unspecific about “penalties”
 - Payment per the wrong items (e.g. query resolution, per check , per table, ...)
 - High cost for repeated tasks (e.g. TLF programming)
 - High tolerance of failed milestones



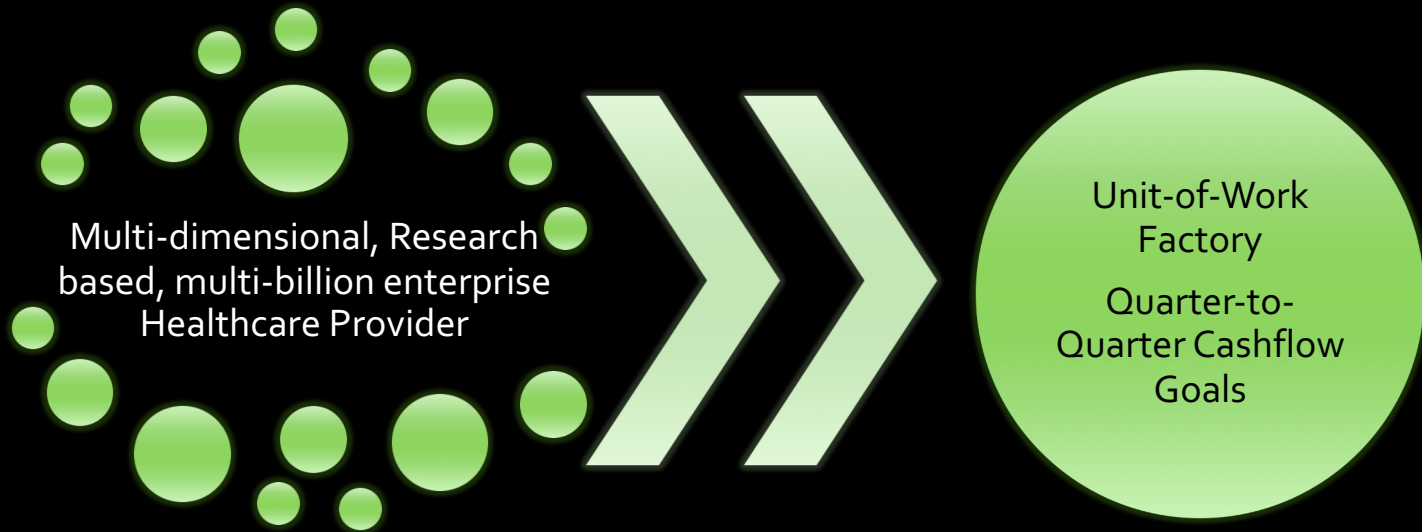


Frequent Dilemmas (3)

- Hands off, vs. check every deliverable in detail
- Changing from one outsourcing approach to another (e.g. multi-CRO to one single “partner”) approach without detailed planning and corresponding lead time
- Expectation mismatch: Sponsor expects flexibility and solution-focused approach, while CRO has a formalistic, one step after the other approach
- Operating models do not fit together, i.e. CRO is much more siloed, where the sponsor has more broadly qualified people



The Operational Mismatch



Pharma

CRO



Ideas for Solutions





Conceptual Organization of VOM

- Governance
- Communication
- Measurement
- Sustained Effort



Governance

- Assert control over vendor counterparts
- Typically there are too many committees; two are usually enough:
 - One higher level committee focusing on long-term review, planning, business strategies
 - One committee which discusses status and issues on operational level
- Adopt meeting frequency to project needs, not calendar
- Ongoing vendor performance review on study level
- Apply Vendor Oversight Plan



Communication (1)

- Single point of contact on a functional level
- Understand and use each kind of communication mode:
 - Face-to-face as frequently as possible
 - Avoid passive-aggressive behavior
 - Co-location of vendor counterparts whenever possible
 - Use of exception reports (instead of status) to enable a focused discussion
- Meetings:
 - Sponsor determines the content
 - Sponsor leads and facilitates meetings with vendors
 - => reaffirms the governance
 - => ensures that the required topics are addressed
 - => productive and efficient meetings





Communication (2)

- Apply fact-based, open and honest feedback:
 - ▣ Feedback focuses on facts and not on subjective information
 - ▣ Feedback provided will be positive and negative, in particular recognizing achievements as well as exceptional performance
 - ▣ Positive feedback boosts morale and the recognition goes a long way in promoting a healthy working relationship
- Encourage proactive engagement on both side of the vendor and sponsor relationship. If something needs to be discussed, the topic should be brought up immediately and nobody should wait until the next scheduled meeting to do it





Communication (3)

- Internal staff as a role models for vendor staff:
 - Transparent, fair expectations not only allow for effective relationship building but provide solid objective data on performance measurements that can be discussed frankly and professionally
- Understand how the collaboration with its team members is perceived from the vendor's perspective
- Appropriate internal communication



Measurement (1)

- Focus on the “Vital Few” measures/reports
 - Keep a small, but predefined, set of metrics that you can speak to, both internally, and with the vendor
 - This gives you objective evidence of excellence or underperformance rather than relying on anecdotal evidence
 - Ask the vendor to keep their own set of metrics as well especially surrounding staffing levels and resource allocation to your project
- Define a time and materials approach to contract as often as possible, i.e. avoid too much allocations under "project management"
 - Will add to the transparency of the costs for the services you are requesting



Measurement (2)

- Some services will be soft skill based and harder to quantify, but there should always be a billable rate and estimation of time required by individuals to complete the job/task
- Process compliance and data quality are interrelated and require review on an ongoing basis – not at the end only
- Operationalize review of deliverables which are less quantitative (e.g. SAP, CSR, TFL), e.g.:
 - Content
 - Accuracy
 - Compliance (with formats and standards)
 - Completeness
 - Timing





Sustained effort

- All of the above have to be sustained throughout the life of the trial or program
- This requires appropriate training and mentoring
- Consistent and repeated messages and support from management
- Documentation
- Consistently apply vendor oversight strategy



Conclusions





For Sponsors to Think About (1)

- Identify areas for internal Process Optimization
 - E.g. Study startup process, close-out procedures, DB lock
- Identify internally defined standards to be developed and to be used by CROs
- Defining “vital few” objective metrics/KPI’ s:
 - Information sources, reporting methods, and application to business
- Align with Key Stakeholders on
 - Functional needs
 - Relationship and control between over all and functional oversight
 - Vendor Performance Oversight approaches

For Sponsors to Think About (2)

- Identify soft-skill training requirements
 - Managing sponsor-provider communication and control from position of authority
 - Interdepartmental alignment
- Determine right size and type of CROs
- Ask your vendor for feedback, ideas and suggestions
- Avoid to become the sponsor that nobody can please



For CROs to Think About

- Foster open, honest and proactive communication
- Demonstrate transparency
- Strive for excellence
- Identify and address deficiencies on the sponsor side
- Don't get tired to suggest improvements on the sponsor side where ever they deem necessary



The W&A Experience

- Typically sponsor's CD organizations are not prepared and not staffed to set up a successful VOM strategy by themselves
- Instead - in case of CRO issues – people move to a different CRO or another outsourcing model
- There is never time or money to set up something right from scratch
- In consequence the learning effect of bad experiences is negligible



The W&A Approach

- There is no “one-size-fits-all” solution for VOM
- Issues might be similar, but sponsors are different
- Sponsors’ key business drivers should drive the solution
- Review of current processes and roles and corresponding adaption
- Identification of a matching CRO(s)
- Vital few metrics
- Train staff
- *In vivo* mentoring



Contact:

Detlef Nehrdich, Senior Associate
Waife & Associates, Inc.

Finding Efficiency in Clinical Research

Known to Know®

(+49) 172 741-8750

nehrdich@waife.com; www.waife.com; [@WaifeAssoc](#)