



PIPMG - Pharmaceutical Industry Project Management Group

Autumn Meeting – 11/12th November 2003 – Crowne Plaza NEC (Birmingham)

OUTSOURCING – A MARRIAGE DESTINED FOR HEAVEN OR HELL?

Chaired by Sarah Dawkins (GlaxoSmithKline)

Introduction

The overall theme for this meeting was the relationship between Contract Research Organisations (CROs) and their Customers, which has parallels in courtship, marriage and “making a go of it.”

A mixture of presentations and interactive sessions was used to examine:

- the facts and figures about use of contract resources
- best practice in initiating the partnership
- a shining example of a successful “symbiotic” relationship
- the true costs (financial and managerial) of outsourced resource
- ways to avoid changes in scope and escalation of costs

Acknowledgements and thanks were expressed to the Chairman and members of the Steering Committee for their joint efforts in organising and running the meeting.

Statistics and Trends in the Pharmaceutical Industry

Richard Halliday (Consultant)

The last decade has seen a shift towards increased outsourcing in many industries. The revenue of leading CROs in the Pharma sector was growing by 60% p.a. during the mid ‘90s. The overall growth, possibly driven by increased regulatory demands, is a product of both R&D-spend and CRO participation. R&D-spend can be estimated at ~15% of sales (so ~\$48bn in 2002) and CRO participation is probably now 15-20% - giving a current estimated spend on outsourcing of \$7-8bn.

The actual figures vary according to company-size, geographical location and type of R&D activity. In 1993, for instance, US companies contracted-out more clinical research and less toxicology than EU and Japanese companies. In 1997, major companies (R&D budget >\$800m) generally allocated a lower proportion of their work to contract whilst small companies (<\$250m) used CROs much more for CMC and regulatory work.

The main drivers for using outsourced resource are currently capacity-considerations and the need for specific technology and expertise. Specialist knowledge and reputation are the frequently cited characteristics defining the best CROs. Loss of control ranks much higher as a source of problems with CROs than does cost – which may explain the high in-house labour costs that customers spend on managing CROs (estimated to be typically 5% of a function’s in-house costs, but much more for smaller companies).

Recent data show that users, whilst often making a decision on a project-by-project basis, tend to select preferred suppliers or have a master contract group. There is understandable caution about a 'one-stop-shop' equating to 'all-eggs-in one-basket,' and concern about intellectual property issues. The intentional reinforcement of strategic alliances and long-term relationships are still quite rare despite the potential win-win benefits.

Interactive Session 1 - Evaluating the Choice

"The Courtship and Pre-nuptial Agreement"

The objectives of this session were to examine:

- the underlying reasons why pharmaceutical companies outsource work (clinical trials, manufacturing, preclinical work etc)
- the ways in which CROs undertake this work
- the ways in which the customers are organised to outsource

There were six syndicate groups in mixed tables representing virtual companies, CROs, small and large Pharma.

Drivers for making an outsourcing decision:

- Capacity (resource-shortfall)
- Need for specific expertise, skills, technologies
- Start-up and virtual companies have no choice but to out-source
- Sponsor companies should concentrate on their core expertise
- Contract-out non-core activity on a project-by-project basis
- A structured approach requires internal resource for:
 - outsourcing decisions
 - definition of the work
 - developing the relationship
- There is often concern about loss of control (placing risk with the CRO)

Evaluation of CROs (and clients):

- Nature of evaluation varies depending on:
 - the degree of in-house expertise
 - the driver for outsourcing (technology or capacity)
 - CROs need to assess their own capabilities and experience
 - Confidence in delivery outweighs cost - within reason!
 - CROs also contract-out to investigators, labs, couriers etc.
 - Personalities matter in developing a successful relationship
 - Meet the people at laboratory-level - they determine the true quality
 - Post-project review is not done as widely and comprehensively as it should
- Some companies have protocols for evaluation
- Some out-sourcing groups, Some managed by line-functions
- Legal, IP and financial evaluation is important

Selection criteria:

- Some large companies have reduced their preferred shortlists
- Small companies tend to make less formal, *ad hoc* selections
- Primary driver of selection tends to be quality > time > cost
- A good working relationship at lab-level is an important factor
- In Clinical studies, selection occurs at different levels
(CRO-> Study Management Organisation-> Investigator)
- Sometimes, comparison is ruthless against a well-defined specification

Project Management of Outsourcing and Best Practices

“The Marriage and Counselling”

Jeanette Evans (AstraZeneca) and Deborah Brewer (Omnicare Clinical Research) AstraZeneca’s project to select preferred suppliers for Phase II-III clinical research included participants from all the relevant line functions and combined their independent ratings of the candidate CROs using an evaluation tool designed to deliver an objective assessment. The CROs had been pre-screened for compliance, quality, SOPs, financial and insurance risk. Additional selection criteria included geographic coverage and consistency, therapeutic area expertise, service-offering, amount of available resource, PM capability, track-record for delivery, flexibility and availability, technological capability and knowledge management.

AZ has framed a clear global clinical sourcing strategy that optimises the value generated from in-house “intellectual” resources and out-sources all non-core activity. This is embodied in a comprehensive methodology – Clinical Outsourcing Process and Study Team Operating Model (COSTOM) – that defines, clarifies and enhances the outsourcing process and facilitates efficient, effective delivery. COSTOM addresses the key principles of resource-allocation, skill-base, joint-team-working, and systems/processes. AZ appoint an internal Study Team to manage the contract in terms of planning, communication and performance.

At the study-level, AZ’s Clinical Study Team Leader works closely with the CRO’s Project Leader, but the 2 teams do not duplicate effort. The benefits of using the COSTOM methodology are consistency of management, empowerment of teams, clarity of communication and decisions, partnership and reduced project-risk. The ‘soft’ side is not ignored – the teams celebrate success and reward achievement of milestones. AZ’s key contact for CRO collaboration is a Clinical Outsourcing Manager (COM).

Omnicare Clinical Research has a Strategic Account Manager to represent their side of this productive collaboration and their own Project Leaders at the study level.

There is a strong emphasis on maintaining a dialogue and shared planning. Recognising that Change-Order can be an issue in any contract, the CRO maintains a cumulative log of changes and a pre-agreed threshold must be reached before revised costs are negotiated. Negotiation of the contract-price is kept separate from operational discussions. Performance metrics are mutual - trends and issues are discussed. Omnicare surveys all the members of the AZ team at intervals to monitor satisfaction. Within the CRO, satisfaction is evident from staff preferring to work on the collaborative contracts in a ‘one-team’ environment.

Interactive Session 2 - What does Outsourcing Really Cost?

“For Richer or for Poorer”

The objectives of this session were to share knowledge and gain insights into different approaches to establishing the real cost of an outsourced programme.

- How good are we at getting robust, comparable tenders and transparency of costs?
- Are we able to understand and measure the real cost?

Transparency of Costs

- Costs are far from transparent and hard to quantify
- Costs are clearer than timelines which are probably clearer than quality (risk)
- Budgets depend on protocols but customer expectations are often fixed beforehand
- Selection on the basis of cost is risky – ask yourself why is it so cheap?
- Real cost is lost time-to-market – false economy if submission is delayed
- Clarity of scope and a change-order log help to control cost over-runs
- Customers may overlook the cost of plant and capital investment needed to ramp-up to a new capability
- Need to make a fair comparison between internal and external costs – does internal project accounting give a fair picture (e.g. of fully-burdened FTE costs)?
- Box-ticking approach can harm the relationship

Calculating the Cost

- Value of doing contract-work includes CRO assets and their management oversight
- Cost of failure and delay is “down-time downstream”
- A good contract is as important as a good plan
- Risk arises from properties of the compound and possible errors in execution
- Costs to be considered include: FTEs, materials, sub-contracts, opportunity, management, travel and meetings
- Potential for duplicating effort
- Outsourcing is a strategic decision based on the cost of owning the capability and the disadvantages of not owning it
- Expect to get more efficiency and benefit from CRO’s economy of scale
- Think of cost in terms of time gained (time/cost trade-off)
- Negotiate hard but fairly - Demand efficiency both in-house and externally

Relationship Management

- Clarify the frequency and lines of communication
- Develop the relationships, the skills and the resource required to do this
- Empower the Project Team Leader to make decisions on contracts
- Plan, and set the tone – take the time to set it up – avoid blame-culture
- Keep the interfaces at two separate levels:
 - Contract and Business
 - Technical and Operational
- There is a tendency to behave contrary to a win/win approach
- At the end of the day it’s still a business relationship

- Degree of duplication varies from zero to a complete mirror-team in-house and CRO
 - Also varies according to the stage of the contract
- Good idea to employ an intermediary expert (especially for virtual companies)
- If possible, try out a new CRO with a small job first

Mission Creep, Avoiding and Managing Change

“For Better or for Worse”

Mike Bowden (Health Decisions)

Mission Creep, defined as a gradual change in a project’s methods and goals, is one of the main factors affecting the relationship between a CRO and their sponsor.

Principally, it results from losing focus on what really matters during the sometimes-chaotic human interactions that generate risk and uncertainty in the best-planned studies. The easiest forms of Mission Creep to spot are Mission Leap (radical change in objective) and Project Transition (expansion into a new area). However, the more subtle forms - Task Accretion and Project Shift (accumulation of new tasks or altered operation of the plan) can lead to argument and resentment. *CRO* – “If it’s so important why won’t they pay for it?” *Sponsor* – “It’s only a small change so why are they charging for it?”

Many of the problems stem from the initial proposal and drafting of the contract. The intended mission may be impossible or misunderstood – worse still there may be subterfuge aimed at minimising cost. Most sponsors would value professionalism above lowest cost. The Request-For-Proposal phase is frequently rushed – a proposal for a multi-million-pound engineering contract would never be expected within 3 weeks with minimal information and at no cost, as sometimes happens with clinical trial contracts of similar magnitude. In an effective tendering process, there is openness and honesty on both sides and clear definition of deliverables but also room for the supplier to provide an innovative approach. It was proposed that good proposals cost CROs money and a more effective tendering process should recognise this cost with a tendering fee. If there are no more than 3 candidates at the RFP stage then this cost can be minimised whilst encouraging CROs to invest in feasibility-testing and not base their proposals merely on a ‘template’.

Investment in effective tendering has been shown to bring benefits in time, cost, quality and risk – the project should have metrics to demonstrate the benefits. Clarity about objectives, strategy, tactics, risks and assumptions minimises the opportunity for mission creep and if change does become necessary it is dealt with in a reasoned way.

Good contracts define clearly: the scope of the work, responsibilities, payment-terms, change-process, communication-pathways, dispute-resolution. With luck, the contract should stay unread on the shelf.

Expert Panel - Key Messages from the Day

“The Value of a Good Partnership”

Mike Bowden, Deborah Brewer, Jeanette Evans, Richard Halliday

The analogy with marriage was upheld during the meeting – which had plenty of controversy and some energetic breakouts. A key message had been that it pays to work at developing the relationship.

Asked whether there was good practice “out there,” panel members had to conclude that practice was highly variable.

There was some debate on whether it is reasonable for CROs to charge for proposals. Customers may consider that costs should be borne by the suppliers as the cost of doing business but:

- Proposals often contain a lot of the CRO’s Intellectual Property
- It should be acceptable to charge for a feasibility study
- A comprehensive evaluation and proposal (~6weeks) could reduce risk that might itself cost up to 15%

Useful web-links for CRO listings

<http://www.technomark.com> (CRO and CPM links)

<http://www.pharmafile.com> (Service Companies link)

http://www.diahome.org/docs/WebLinks/Links_index.cfm DIA links

<http://www.instituteofclinicalresearch.org>

Phil Dolamore 27th November 2003