

VIRTUAL IS A NECESSITY

By Anthony Walker, PhD, December 2009

The joke going round the airline industry is that if the Wright Brothers were around today, Orville would have to fire Wilbur to save costs. Of course, the same is happening all round, but the novelty in the life sciences sector is that the current pandemic of the Money Shortage Virus is not confined to biotech and is hitting the majors as well. Large pools of experienced professionals are being released, with many setting up shop as consultants. As ever, during cyclical downturns, the vogue is to make a virtue of necessity, and the mantra of the moment is 'virtualize'. In reality, virtual is not new, neither is it a panacea, and indeed, it can be abused. Nevertheless, outsourcing can continue to underpin business efficiency and even promote value creation providing that it is implemented intelligently.

Virtual is not new

Biotech has always been virtual to one degree or other if for no other reason than economic efficiency. Biotechs seek external input in intellectual property, regulatory affairs, product development, market research and a whole host of other functions that may be considered 'mission critical', let alone those that are non-core. The same is true of the pharma, device and diagnostic majors, as evidenced by the large volumes of work placed by these companies with CROs, law firms, accountants, patent attorneys, etc.

Over recent years, the pendulum may have swung towards more outsourcing, but this has only really been an extension of a well-embedded trend. The current financial crisis, decreasing returns on R&D expenditures, an increasingly hostile reimbursement landscape and impending patent cliffs have simply exaggerated the need for operational efficiency. Sometimes, it just requires a simplification of overly complex internal structures and processes that have sclerosed the managerial arteries of the lumbering giants (hence the massive downsizing which shows no signs of

abatement). Other situations, however, call for more virtualization/outsourcing, but getting this right requires high level expertise and experience and careful selection of the outsourcing partners.

Outsourcing partners: horses for courses

Focussing only on life-science specific outsourcing (setting aside accountants, lawyers, IT services, etc, from this discussion), three archetypal service providers can be defined:

CROs: 'industrialized' majors in each segment, with a fringe of niche players. Business model driven by offering standardized services, usually with little true customization. Quality of service ranges to either extreme; one frustrated Big Pharma clinical researcher calls CROs "the people who work from 9 to 5 so we have to work from 8 to 10".

Freelancers/Interim managers: solo practitioners; usually ex-life science company (senior) managers. Fill a key role where full-time appointments are not justified and/or feasible (job too small; company too small; cash runway insufficient). Can also play a highly valuable role as intermediaries between CROs and their (large or small) clients, making sure both sides stay honest to forestall the type of frustration described above.

Consultants: experienced, specialised professionals with:

- the ability to reach rapid and accurate diagnoses of managerial or strategic issues;
- the skills and networks required to propose and implement effective solutions; and
- the integrity and experience to know when a situation is beyond their ability to contribute. Consultants range from specialist partnerships to major multinational firms.

It may seem trivial to select the right type of partner (CRO, freelancer or consultant) for any given situation, but in reality these decisions are often taken without appropriate forethought. For example, it seems natural to turn to a CRO to manage a clinical trial, and indeed, for a large, multinational phase III trial this may be spot on. But for a small and/or specialized trial, the CROs' tendency to force-fit the situation to their standard methodologies may be counterproductive. In our experience, it is very difficult for a large CRO to train their staff in 'unusual' techniques and procedures, not least because of their high staff turnover, and for non-standard trials it is usually better to engage a bespoke team of skilled, flexible professionals. In these situations, we have seen highly effective management of trials by freelancers/interim managers, who may either engage relevant professionals directly (CRAs, GCP auditors, biostatisticians, etc.) or who may contract with a specialist CRO with particular strengths in the disease/technology/trial design in question.

Likewise, there are situations where the specialization of a freelancer is ill-matched to the breadth of the issues faced. Sometimes, commercial strategy questions masquerade as clinical trial issues, and their solutions require input from more than clinical researchers. In those cases, experienced consultants, appropriately engaged and directed, add significant value.

The Role of Management in this Virtual World

It has been suggested that an entire management team can be composed of freelancers and consultants, i.e. taking the virtual concept to its extreme. We disagree with this proposition. It is a construct that is well suited to endeavours where all goes well, but does not extend to the life sciences industry where, at the very least, biological variability of one sort or another conspires to derail programmes at multiple, often unexpected stages.

Our firmly held belief, based on the Alacrita team's experience as consultants, as freelancers

and as senior managers in biotech and big companies (poachers, gamekeepers and game?) is that there is an optimal point between fully-integrated and fully-outsourced – it is a bell-shaped curve. A project or company needs a dedicated, full time core management team with enough skin in the game to keep them fighting in the trenches when challenges reach that critical point where those who are more detached would simply walk away. And in our model, one of the key responsibilities of the core management team is to decide which type of external input is needed for each specific situation.

The bottom line: cost-effective outsourcing

Outsourcing partners may be:

- full-service or highly specialized
- multi-facility, multi-national or single location

Traditionally, major players in both the CRO and consulting industries have tried to match their scale and geography of their clients. This has had the unintended consequence of also matching their somewhat bloated cost structures as well as the internal tensions between the geographic and functional dimensions of the management matrix. These are large business machines with significant overheads in need of constant feeding. Clearly, complexity is incompatible with cost-effectiveness, and we believe there is a current trend in favour of smaller, nimbler service providers. Big Pharma is trying to emulate biotech in many ways, including in their choice of consultant or other outsourcing partner. They no longer want the luxury and the costs of the Mayo Clinic; they want House, M.D. with a team of specialist associates, operating in an innovation centre with low overheads.

About the author



Anthony Walker, PhD has worked for ICI in Berkshire and Brazil; consultancy firms Arthur D. Little and The Wilkerson Group, and biotech company Onyx.