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THE ONGOING DALLIANCE BETWEEN THE WEALTHY PHARMACEUTICAL COMPANY AND THE SERVICE ORIENTATED CLINICAL CRO

If you were to ask most leading executives within Contract Research Organisations they will tell you that blue chip Pharmaceutical companies outsource their critical clinical research studies to them. Ask the same question to leading executives within pharmaceutical companies and they will tell you that they never outsource critical pivotal studies to the CRO industry.

Who is telling the truth?

In reality, both, merely the perceptions are different!

Pharmaceutical R&D spending has continued to spiral upwards over the last decade. However, output in terms of products has decreased. As companies drive to increase the efficiency of their R&D, there is greater focus on the need to manage more closely their internal and external resources, leading to increased growth within the contract research sector, with estimated spend on contracted services at approximately US\$10 billion in 2001.

As the Pharmaceutical outsourcing budget has grown, so have the large global CROs. Growth has been exponential but all too often they have developed in the image of the global pharmaceutical sector from where their clients are based. Having begun life as small, flexible, customer



focused, niche service companies, have they become global, massive, internally focused and inflexible? Are they more interested in satisfying shareholders than customers?

In the industry today, there are more than 1500 CROs globally. The majority are niche providers with approximately 20 large companies whose revenues exceed US \$50m per annum. The paradox lies in the fact that sponsors want an increasingly broad service offering, as exists within the global players, coupled to a greater level of niche expertise, flexibility and customer focus, as exists within the niche providers. Ironically, at times, the large CROs will outsource to niche providers when they do not have the expertise required in certain regions to guarantee the quality required. This is currently particularly true within Eastern Europe where local and interna-

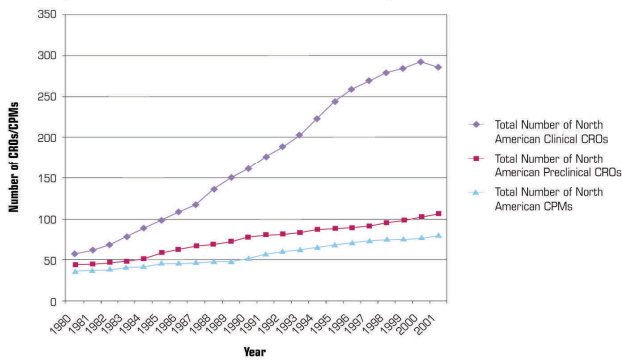
tional companies are increasingly working closely together.

"Our business model as a highly specialised niche service provider, supported by the most advanced technology, has proven very successful. This focused, non-generalist approach differentiates INC research within the industry"

Kevin Logan PhD,
President of INC Research

As outsource spend grows and the pressure for success intensifies, sponsors are taking a more proactive approach to outsourcing: When to outsource? Where to award the contract? How to manage the relationship and the nature of the contract? The relationships are evolving and an increasing number of CROs offer services for entire development programmes to be outsourced

Figure 2: Growth of North American Contract Organisations



and many virtual pharmaceutical companies have strategies that are built around this concept.

In 2002, the increased use of technology has allowed smaller niche service organisations to compete more readily due to their ability to rapidly share information globally within project teams, thereby avoiding the need to replicate talent in each and every location and country. Similarly, an increasing trend towards niche providers, developing networks and alliances with “competitors,” is allowing them to compete increasingly with the large CROs. However what they cannot compete with is the economies of scale and the “preferred provider agreements” that exist historically between the world’s largest pharmaceutical companies and the global CROs – more formal networks might facilitate this.

Despite the global downturn in the economy, the effects of September 11th and the continued M&A activity within the pharmaceutical sector, the number of CROs continues to grow, with particular growth within the European market place. The number of companies continues to grow and those public companies report continually growing revenues but this is not necessarily mirrored by increased profitability. Of the top 25 CROs (by revenue) 23 indicated growth in their annual revenues in 2001 (compared to 2000), which is an indication of sector

growth of almost 14%. As shown previously, the growth rates of the Top Five at 8.5% were significantly lower than that of their smaller competitors at

Field	Region	Number of CROs in	Number of CROs in	Growth Factor
Clinical	Europe	53	441	8.3
Preclinical	Europe	52	167	3.2
Manufacturing	Europe	156	313	2.0
Clinical	Nth America	57	285	5.0
Preclinical	Nth America	44	105	2.4
Manufacturing	Nth America	36	78	3.2
Total	Global	398	1389	2.5

22.8%. Clearly the sector still has a rosy future with forecasts predicting that the CRO market will grow to in excess of US\$16 billion by 2005.

If the past, present and future is all so rosy, why have the last 5 years been so tough for the service sector, and in particular clinical CROs? For a long time the pharmaceutical sector has seen CROs as a “necessary evil” only turning to them when there was insufficient internal resource. At times, the CRO sector has exacerbated this feeling in the way in which it has “prostituted” itself by securing business on price alone, without focus on quality or added value. More critically, many CROs have struggled to attract and hire the top quality professionals that they need to become “centres of excellence”.

Worse than this, throughout

the 1990’s and into the new millennium the sector has struggled with staff retention. It has reacted to this by promoting from within to ensure that clients have the perception of continuity within their projects, nowhere more prevalent than within Project Management. Every time a lead CRA is promoted to a position within Project Management for this reason, companies dilute their quality and capability within Project Management. CROs ultimately have a product; the project that is handed back to the sponsor upon completion. Technology aside, the quality of their product is directly influenced by the quality of their project management. Hiding behind

sources are their only assets. Yet, all too frequently staff report that they are treated with disdain and are considered disposable. They are your only assets. CROs must learn to cherish them and appreciate that they will only achieve their objective of being the best by seeking to recruit the leading talent. Once identified and recruited, these individuals must be nurtured, developed and given the flexibility to pursue personal growth objectives along with those of the organisation. Talent often comes with a low boredom threshold and these individuals may need scope, variety and the opportunity to stretch themselves, not just repeat the same tasks over again because “they are good at them”.

“The importance of hiring individuals who combine significant indication specific study experience with clinical experience, has been the key to our success”

Kevin Logan PhD, President of INC Research

Within their recruitment strategy CROs must look ahead and hire for the future of the business, rather than for their needs today. Whilst balancing resources is a delicate and difficult matter, recruiting “behind the curve” ultimately results in short term decisions. It will become increasingly imperative that the service sector thinks and hires more creatively, identifying talent that will suit their needs as their business continues along the path of rapid change, development and evolution over the next few years. That talent will change and soon the traditional look of a CRA or a data manager will be different and the companies that invest will benefit. Project management skills will be at a premium and again companies will need to hire more wisely and invest in training and development, not relying on the employees to learn whilst on client work. Few companies know what makes a good CRA, a good Project Manager or a Data Manager. The sooner that these are qualified and quantified, the stronger an organi-

multi coloured Gant charts will not replace the lack of experience that is witnessed when this occurs. We are currently witnessing success within Project Management focused CROs. This is no coincidence, and the CROs that are making a positive impact within the marketplace, remembering that perception is reality, are reaping the rewards for their investment in project management. Arguably, all these companies have done is to take a step back and ask themselves some very basic questions: “What do we do?” “Who are our clients?” “What do they expect from us?” “How can we ensure delivery?” “How can we exceed their expectations?”

When put like this it seems terribly simple and obvious.

CROs talk a great deal about their people and the fact that these invaluable re-

sation will become and the more rapidly they can move towards Best Practice in all areas. This will differentiate the leading CROs from the rest and the return on investment, in a growing sector, will be significant.

One of the great ironies within the CRO sector is that they espouse the value of outsourcing clinical services to the experts, namely themselves. Their sponsor's core business is Sales & Marketing, not clinical research, allegedly. Much like the proverbial "cobbler's children", CROs continue to manage much of their own talent recruitment, management and development. This is not their core business and they do not have the objectivity that is required for a sector where people are so critical to the success of the business. The same is true with the Pharma sector, but the margins and resources make this less critical, coupled to the fact that historically the industry invests more in the training and development of its people. They should, however, pay critical attention to the individuals that they recruit or promote into contract management positions, as this is frequently a role with a series of skills traditionally non-existent within product orientated companies. For both sectors, a greater level of talent will be required in the future, from a shrinking talent pool an increased emphasis will need to be placed on how to identify, secure and retain the most talented professionals to support your business. As a simple rule, ensure that the growth expectations and needs of the individual are married to those of your organisation, and where appropriate to those of your clients.

Preferred provider agreements have become increasingly complex and common. Outsourcing departments within the world's largest pharmaceutical companies have become increasingly influential, as have their procurement departments. Herein lies a potential conflict with one group focused on quality of research and suitability of resource and service provider and the

"Relationships between partners are not a nice to have but an absolute essential if successful development is required"

Graham Belgrave, Director of Global Grants & Contracts Europe, International & Japan, GlaxoSmithKline R&D

other potentially focused on cost savings. The drive for such agreements has benefits for the CROs as it provides security and a predictable revenue stream, yet there are many examples where these agreements have in fact led to the breakdown of relationships between sponsor and service organisations. This has often been blamed on complacency on both sides and an erroneous perception that with the relationship established, neither party has to continue to put the time and effort into the relationship to ensure its continued success and growth. These agreements are between companies, yet the relationships are between people and therefore require constant investment.

Too often Pharma will outsource to "experts" then micromanage the CRO and establish too many constraints removing any decision-making authority. Once again, the time has come for increased transparency and honesty. CROs must not hide behind slick marketing and be honest about capability, resource levels and areas of expertise. Sponsors must show more trust, be prepared to pay for valued services and must support the CRO in their endeavours to achieve success. The nature of the relationship must evolve and mature in a mutually beneficial manner.

They must re-invent the process of working together to avoid duplication, and to optimise overall efficiency and effectiveness.

Leading CROs will need to have the following attributes and skills:

- ◆ Exhibit real project management expertise
- ◆ High levels of technical and

- process expertise
- ◆ Flexible resources
- ◆ Customer focus
- ◆ Critical access to investigators and patients
- ◆ Ability to reduce sponsors' overheads / costs
- ◆ Improved quality of research and data
- ◆ Ability to reduce development time
- ◆ Broad geographical coverage in key markets
- ◆ Expertise of the specific regulatory requirements for the study
- ◆ Desire to partner and understand customer needs
- ◆ Readiness to genuinely risk share and invest in the relationship
- ◆ Maximise the advantage of technology, electronic media and communication channels
- ◆ Take and share ownership
- ◆ Hire, develop and retain talent
- ◆ Continually invest in developing relationships at all levels
- ◆ Be prepared to say "no"
- ◆ Work openly, develop trust and behave with integrity

Despite much discussion, there have been limited numbers of genuine examples of partnering between CROs and Pharma sponsors, in spite of much dancing around the subject and a perceived and much spoken about move towards this. We have been moving towards partnership for almost 10 years, but are still no closer. Are the goalposts moving or are we moving in the wrong direction? Perhaps it is both and another reflection of the difference between CROs perception of sponsor expectations and the real expectations. Similarly, there is no doubt that the sponsors' ability to accurately communicate their expectations, and then stick with them, requires further consideration. There is also the danger that these partnership relationships will merely replace the preferred provider relationships of the 1990's without any real breakthrough

that benefits both parties. In order to be of maximum benefit on both sides there must be increased trust and mutual respect, both of which must significantly exceed the situation as it exists today. The independence of the CROs must not be controlled or violated through the desire for priority focus from key sponsors. Whilst risk sharing is becoming more common, this may at times be a misnomer, with contracts primarily developed on a cost and materials basis, then adapted to one where the CROs take increased visibility and risk.

One area that can be addressed, and must be, is the establishment of true parameters for measuring the performance of CROs. There are many examples where milestones have not been achieved and everybody has their horror stories, but is this always the sole responsibility of the CRO? Are CROs often used as a scapegoat? More crucially, how often do CROs exceed expectation, deliver on time, above expected quality and within budget? The honest answer is that we do not know, but we should. There is no doubt that this occurs and all concerned should celebrate publicly, visibly and audibly, but they do not. This must change. The service sector and clinical CROs in particular have achieved much of merit over the last 20 years, will continue to do so and should be recognised for this.

"Clinical Development performed by a Pharma company is not a cheap exercise. Why then expect the same work carried out by a CRO to cost any less?"

Graham Belgrave, Director of Global Grants & Contracts Europe, International & Japan, GlaxoSmithKline R&D

The big CROs continue to grow and add greater diversity to their service offering, potentially having sufficient internal services to mirror those within a traditional pharmaceutical company. The small niche CROs have to make a difficult decision; do they remain as successful niche organisations or do they look

to grow or acquire to become a major player in the market? Some niche players have destroyed their own business by embarking on the latter route, others have been highly successful. The dilemma exists when you are a niche player that is enjoying success and almost by default being put under pressure to grow, provide a broader range of services, expand your coverage and become a "Big CRO".

Where do you want to position your business and how do you wish to work with your customers?

**"Do you put revenue
before relationship?"**

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