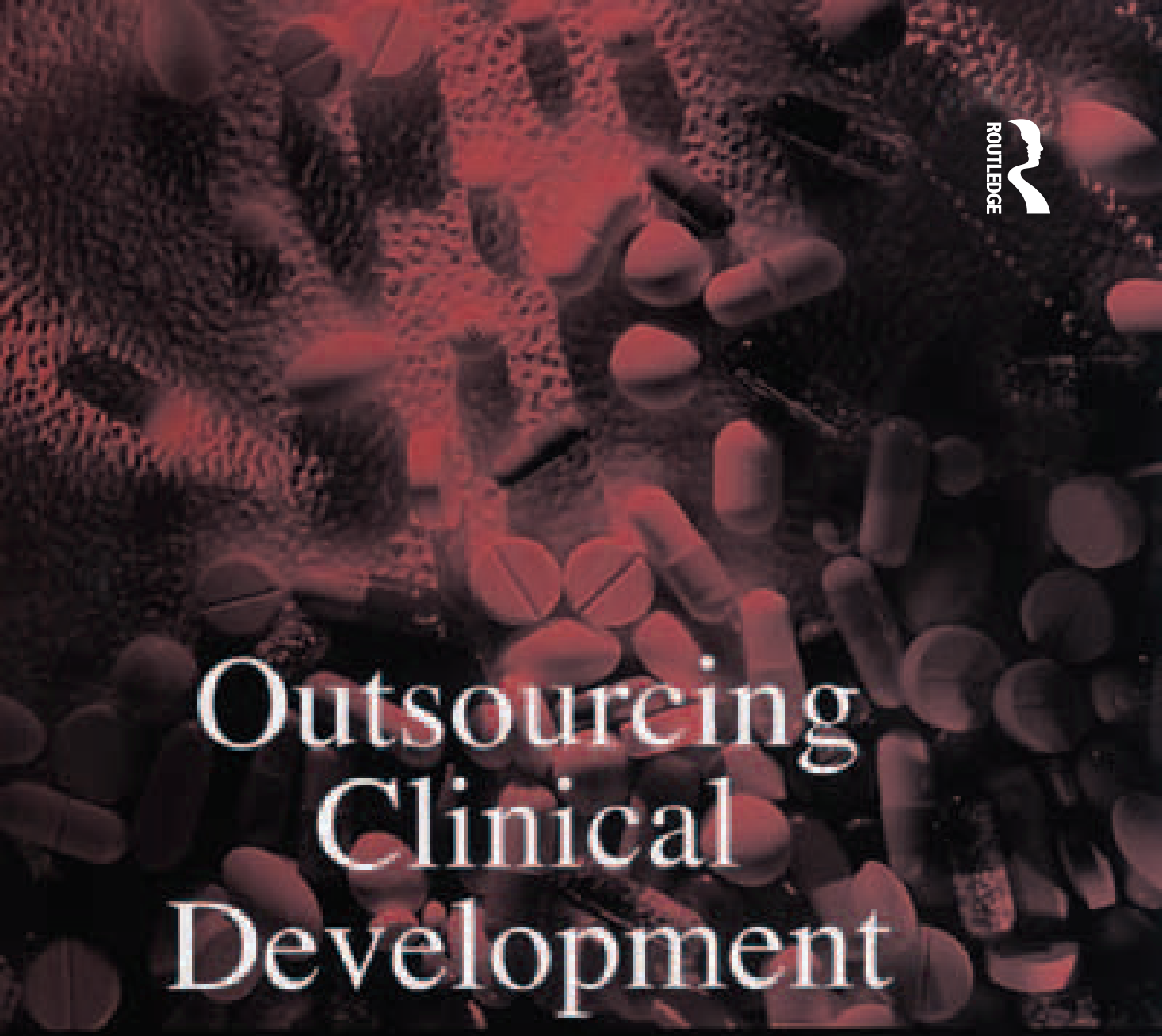

Outsourcing Clinical Development

Strategies for Working with CROs and Other Partners

EDITED BY JANE E. WINTER AND JANE BAGULEY

IN CONJUNCTION WITH THE PHARMACEUTICAL CONTRACT MANAGEMENT GROUP

A **Gower** Book

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In 1989 Jim started his own consultancy and co-founded Cavendish Partners, now merged with Right Coutts, a firm specialising in career counselling and coaching. He has written several books including *Cost Effective Personnel Decisions* and *Giving Feedback* and workbooks such as *Team-Based Problem Solving*.

Jim has a degree in Behavioural Science, a Masters degree in Manpower studies and a PhD in self-employment.

Michelle Cuddigan is a managing consultant working in the IBM Business Consulting Services Life Sciences team in the UK. Michelle has more than 15 years' experience working in and with the pharmaceutical R&D sector. She has worked with a range of clients in the areas of R&D resourcing, outsourcing strategy, performance management, and organisational change. Michelle has a Pharmacy degree from Trinity College Dublin and also holds an MBA.

Smita Desai is Vice President, Business Development & Business Services Europe, Quintiles Ltd. A qualified pharmacist, Smita has 20 years' experience in the UK and global healthcare industry. Commencing in sales with GlaxoSmithKline (GSK), Smita gained extensive marketing experience in product management roles within GSK and underpinned this with a marketing degree. A ten-year period in international healthcare communications gained through Edelman Worldwide and The Shire Hall Group followed. This enabled invaluable experience to be gained in strategic planning, professional relations, patient advocacy management and public and government affairs management.

Smita joined Quintiles in 1999 responsible for Strategic Business Development. Her current role as head of the European product development business development function has enabled her to build upon her career experience. Her role combines strategic planning and management of Quintiles' European BD function, with strategic involvement with a number of key customers.

John C. Easton is the Director, Global Clinical Outsourcing for AstraZeneca, responsible for leading the R&D outsourcing community in AstraZeneca which in turn manages external delivery of Phase I-IIIB studies through a limited number of preferred providers.

John began his industry career in 1985 as a CRA with May & Baker (Rhone Poulenc). In 1988, he co-founded the CRO Campbell Charles Associates, later working for BIOS before moving to Omnicare Clinical Research in 1996 where he held the positions of Vice President, Business Development Europe, Vice President Worldwide Sales Administration and General Manager for Northern Europe.

Before joining AstraZeneca in 2004, John lived in the US where he was Vice President, Worldwide Account Management at PAREXEL.

John holds a BSc and PhD from the University of London.

Jean S. Edwards is the European Procurement Executive, Eli Lilly & Company Ltd. Jean joined the Procurement Team at Eli Lilly in October 2002 and is responsible for the coordination of clinical outsourcing across Europe and ensuring that Lilly gets best value from their clinical suppliers.

Prior to joining Lilly, Jean spent most of her career with Bayer working in Clinical Research, Quality Management and Contract Resource Management Groups. In her last 18 months at Bayer, Jean was part of the Global External Supplier Management Team responsible for Europe & Overseas.

Carl Emerson is Senior Manager in Clinical Procurement for GlaxoSmithKline Biologicals. Carl started his life as a chemist within GSK, and then moved internally to a number of different roles, before commencing his career in contract management within clinical development. After 15 years, he moved to Celltech where he spent four years. At Celltech Carl pioneered contract management within the company as a new function to drive value in the supply of services. In May 2005 he returned to his origins at GSK and joined the vaccines business in Brussels.

Clinical Procurement is a new discipline in GSKBio and Carl is responsible for driving best procurement practice globally for all spend in the clinical area.

Alan Morgan is the Global General Manager of the Phase II-IV business of MDS Pharma Services, responsible for Clinical Operations, Data Management and Biostatistics, Regulatory Affairs, and all the commercial operations of the business in 20 countries. Prior to joining MDS, Alan spent five years with Covance, initially in finance roles, but latterly as General Manager for their Phase II-III business in Europe, Latin America and Asia.

His initial career was in pharma, including seven years with Glaxo Wellcome and ICI Pharmaceuticals in various business financial roles. Alan is a Graduate of the City University Business School in London, a Fellow of the Chartered Association of Certified Accountants in the UK, and is based in Pennsylvania.

Paul Ranson spent the early part of his career as an in-house lawyer for Smith Kline and Merck Sharpe & Dohme. He is a specialist in the commercial business development and regulatory aspects of the above industries. He has written and lectured extensively in legal issues for the sector including on licensing and outsourcing within the sector. His publications include six report-length papers for the FT, Bridgehead and Legalease. He is on the Legal Issues Committee of the ABHI, coordinator of the Ethical Medicines Industry Group (a grouping representing the interests of small pharmaceutical companies) and was a member of a local Ethics Committee for five years.

Emma Sabin has a degree in Applied Biology and a PhD in virology. She has worked in the pharmaceutical industry for ten years, with roles in Data Management, Project Management and Business Development for both pharma and CRO organisations as well as in Medical Education and PR.

Emma joined the Contracts and Outsourcing group at Pfizer in 2002, and, as Director, Regional Site Lead (Sandwich), now manages the Regional Centre team responsible for the global outsourcing of all services associated with early and full development compounds that are developed by the Sandwich site. Emma also fulfils a leadership role with regard to the Contracts and Outsourcing organisation globally.

Jeff Thomis is President, Clinical Development Services & Phase I/Exploratory Medicine, Europe, Quintiles Ltd. He has been in this role since 1998. The role includes selling and delivery services of project management, clinical monitoring data management, statistics, drug safety, regulatory affairs and phase/exploratory medicine.

Before joining Quintiles in 1997 as European Head of Cardiovascular Strategic Business Unit and General Manager of the Benelux office, he spent 21 years at Bristol Myers Squibb in Europe and the United States, and was involved in the successful development of a number of anti-infective and cardiovascular compounds. Positions held at Bristol Myers Squibb were: Assistant Director Clinical Research, Benelux; Director Clinical Research, Scandinavia; Head of Cardiovascular Research, Europe; Head of Medical Development, Europe, and Director Infectious Diseases.

Dr Thomis is a qualified pharmacist with a PhD in pharmaceutical sciences from University of Leuven, Belgium.

Nadia Turner is a pharmacologist with 19 years' experience in the pharmaceutical industry. She has worked in both pre-clinical and clinical research and as a consultant specialising in outsourcing. Nadia joined Zeneca as Development Strategic Sourcing Manager, and following a spell as a Global Development Project Manager, she took up the position of Associate Director, Global Development Sourcing at AstraZeneca leading a cross-functional team to develop and promote sourcing best-practice decision-making, implementation and evaluation across the global organisation. Nadia moved back into Clinical Development in 2002 as Global Account Manager to lead the relationship management with one of AstraZeneca's preferred suppliers – a role she fulfils today. She has latterly been leading a project to evaluate novel sourcing options for AstraZeneca's

oncology clinical development portfolio and is currently involved in developing and implementing a new Operating Model for outsourcing within Clinical Development.

Nermeen Varawalla, Vice President Business Development, leads the international (ex-US) business development team at PRA International, a leading CRO. Prior to this, Nermeen was the founder of PerinClinical, an India-focused CRO. Before that she worked with Accenture's Business Strategy Consulting Practice specialising in drug development.

Nermeen received her medical training at the University of Mumbai, India, before being awarded the Rhodes Research Fellowship to the University of Oxford for her doctoral research. Nermeen then practised as an NHS specialist before obtaining her MBA at INSEAD.

Rikke Winther has headed up Lundbeck's pre-clinical and clinical Contract Management function during the last five years, responsible for the outsourcing process, CRO management, preferred provider agreements and the development of future outsourcing strategies. Prior to this, Rikke worked for eight years within clinical bio-analysis/pharmacokinetics and within CRO Project Management, as Asian Business Development Manager and as a Country Manager.

Rikke is a member of the Pharmaceutical Contract Management Group (PCMG) and Pharmaceutical Outsourcing Management Association (POMA) and regularly presents for both groups.

The PCMG would also like to thank Jacqueline Abbas (Kyowa) and Barry Overton (Cambridge Antibody Technology) for their valuable contributions to Chapters 2 and 6.

Foreword*

John C. Easton, *AstraZeneca*

AN HISTORICAL PERSPECTIVE

The original premise for outsourcing was that it allowed a corporation to trade fixed costs for variable costs, so improving leverage on infrastructure and providing an alternative to building in-house capacity to the levels required to meet peaks in demand. This premise had the added upside of removing investment constraints during periods of high growth by facilitating 'instant' access to capacity and it is as valid today as it was 20 years ago.

As the capabilities of service providers grew, so the segment of process or manufacturing in which they specialised became a core competence. Concurrently, their own financial imperatives, together with competitive market forces, drove them to deliver at increasing rates of efficiency with the result that outsourcing became a more cost-effective method of delivery. Thus a further point of leverage was created for customers.

More recently many of the largest corporations, from auto manufacturers to financial institutions, have struggled to respond to major shifts in the global economy and have faced acute financial pressures as a result. They have had to learn a whole new set of skills in order to drive improved bottom-line performance in the face of acute pricing pressure and stagnating sales growth.

Into this 'challenged' environment came the related solutions of extended outsourcing and managed services. These solutions improve balance-sheet metrics (through the sale of pieces of infrastructure and/or staff to a provider, so generating capital), while dramatically changing the relationship between fixed and variable costs (by renting the capability/resources back from the provider) at the same time as benefiting from improved productivity in the delivery of that capability (as the provider drives

* This Foreword is based on an editorial published in *American Pharmaceutical Outsourcing* in January 2005.

'commercial' grade utilisation out of what had previously been an overhead capability). Corporate information systems (IS) and corporate finance functions have operated against a background of provision through managed services for many years. Today, IS managed services is a multi-billion dollar industry worldwide.

OUTSOURCING AS A STRATEGIC ENABLER

Why was outsourcing able to deliver strategic benefit for these corporations? The simple fact is that outsourcing was embedded in their operating model and their outsourcing strategies were continually aligned with strategic business needs. As their needs moved from basic capacity management to meeting shareholder value challenges, so their outsourcing strategies evolved to include increasingly radical solutions.

A good example of this alignment was described recently in the *Wall Street Journal* (13 June 2004). The 'Big Three' auto manufacturers in the US have been facing intense pricing pressure for some time now and as they searched for a way to respond, there emerged a strategic opportunity to leverage low component manufacturing costs in China. However, labour agreements back in the US made it difficult for the auto companies themselves to leverage the opportunity directly. The answer? Make their suppliers manage outsourcing to China on their behalf! The auto companies set the quality standards and the price, but they leave it up to the component suppliers to work out how and where to outsource off-shore in order to meet the two key business needs of their customers – fit-for-purpose quality at the lowest possible cost.

THE STRATEGY GAP IN BIG PHARMA OUTSOURCING

Over the same timeframe as these developments, big pharma has faced most of the same challenges, albeit lagging perhaps a few years behind the sectors identified earlier. The early 1980s saw regulatory data demands burgeoning while resources were hard to come by and leadership teams were unsure of how to manage in such a high demand growth scenario. So the contract research organisations (CROs) concept took root and began to offer legitimate capacity management solutions. Since then, big pharma has made more or less continuous use of traditional CRO services as a tactic in the short-term management of capacity.

Some have also flirted with the concepts of extended outsourcing – a small number of CROs have made acquisitions of part of a customer's infrastructure (in return for a transient guarantee of an associated revenue stream) in order to achieve post-merger consolidation of redundant assets for the customer. And of course, most recently, Wyeth implemented the first significant managed services type solution in clinical outsourcing when Accenture acquired Wyeth's clinical data management function.

But for the most part, our outsourcing strategies are disconnected from our corporate strategies and our outsourcing behaviours remain wedded to the most basic outsourcing modalities.

HOLDING BACK

What is holding us back and preventing us from tapping this potential source of advantage?

First, we tend to dispute the economic dimension of the benefits case for outsourcing. Intuitively, though, the answer is clear – even if compensation structures are equivalent to big pharma, CRO infrastructure and travel policies are generally inferior. CRO management structures are significantly flatter (leading to lower overheads). Furthermore, CROs are expected to perform at much higher levels of productivity than our own functions in order to meet our expectations and in order to generate profit from a workstream that, for us, is an overhead function. Finally, there is a common perception that CROs make big profits but, in reality, CRO margins are of an order of magnitude less than big pharma's. Outsourcing therefore has to be cost effective – according to a recent study by Datamonitor (*Pharma Times*, May 2004), 74% of German companies and 63% of UK companies in the sectors examined outsource primarily to gain economic benefit.

Secondly, our vision of what outsourcing really offers is constrained. The *Engineering Management* magazine of the Institution of Electrical Engineers (IEE) in England recently carried an article on outsourcing in the engineering space – the outsourcing model in their domain is mature and they describe the various dimensions of outsourcing in the following way:

- Outsourcing entails using external providers to perform recurrent, normally internal, activities or to facilitate profound change.

- Providers assume specific authority and deliver defined services, over specified periods, under agreed pricing regimes.

- The primary driver underlying outsourcing is the incessant need to improve competitiveness and to achieve peak performance by using best-in-breed providers in any activity that is amenable to external fulfilment, and is non-core and not a specialism of the customer.

If we run a quick gap analysis between our world and these proven benefits, then the first part of the first statement would certainly be found to be true – we do outsource normally internal, recurrent activities. However, we do not outsource in order to 'facilitate profound change'. From the second statement, we can certainly meet the requirement that our providers deliver defined services, over specified periods, under agreed pricing regimes, but we are not good at delegating specific authority (see later). But the most revealing gap is demonstrated by the final statement which shows a fundamental contradiction in our outsourcing model. We all go to great lengths to select 'best-in-breed providers', and invest in protracted and costly assessments to achieve this, and yet we eventually use them as little more than paid hands.

Finally, the third, and perhaps most critical, driver for the lack of evolution in clinical outsourcing is our internal conflict around core competencies. Datamonitor's report found that 'new breed pharmaceutical companies will succeed only by keeping in-house the intellectual capital critical to success and outsourcing the rest'. Thus the critical question is – which competencies are actually core and critical to success?

Most big pharma have vision and mission statements that are built around 'innovation in product development', 'meeting un-met clinical need', and so on. None of them mention an aspiration to be best in class in running clinical studies – however, this *is* one of the core missions for most clinical CROs. If we look again at the first statement in the UK IEE's definition of outsourcing we see that 'normally internal' functions are outsourced. Inherent in this statement is the assumption that internal capacity in a particular function reduces as outsourcing of that function increases. This has not happened in the case of clinical outsourcing. As a result there is conflict between the competencies that the business model *requires* to be core and those that the grass roots of the organisation *believes* are core.

RECOGNISING OUR NEED

If we look at our own challenges today, they line up with those other industries have faced and dealt with in the last ten years using outsourcing as a part of their response. In 1998, PriceWaterhouseCoopers (now IBM Consulting) identified that the big pharma business model had a longevity issue (in their *Pharma 2005* suite of reports). Their 'Value Builder' model even forecast and modelled the difficulties that we would face in delivering future value to our shareholders. Since then, big pharma sales growth has, in general, slowed while growth rates in R&D expense have been maintained or even accelerated. Share prices for the largest pharma have, in general, fallen and market capitalisation for many big pharma today is lower than it was in 1998. And now, of course, we have the threat of price benchmarking against generic alternatives to add to our challenges.

The responses that we must make have been clear for some considerable time – we must reduce development costs by 30–40 per cent while at the same time significantly shorten development cycle time in order to drive new levels of productivity. These should be the strategic goals to which our outsourcing strategies are aligned.

RESPONDING TO THE CHALLENGE

Pharmaceutical, biotechnology and device company spend on CRO and laboratory services has shown sequential double-digit growth rates for many years now. The market broke through the $10 billion threshold for the first time in 2003 and most analysts forecast continued double-digit growth over the next three to five years. Others forecast significant growth rates in the level of clinical development activity that is outsourced (without attaching dollar estimates), with one observer predicting that the number of companies outsourcing 60–100 per cent of activity will double between 2003 and 2008.

However, if we are successfully to use outsourcing as a vehicle to meet our corporate challenges then the future growth in spend forecast by analysts is going to have to be based on a very different set of drivers than those which created historical growth. Our outsourcing strategies must balance the continually increasing regulatory data burden on drug development with the need to reduce the total costs of development by more than 30 per cent. This offset will not be achieved by simply driving down provider rates – even if we completely removed our provider's profits, we would barely dent the challenge – but instead will require radical delivery solutions. We will need to begin to work with our providers and understand how we can capitalise on their more agile operating models in order to move our own thinking forward. We will (finally) need to address the conflict of competencies discussed earlier and move to a model like that described by the IEE where we use best-in-breed providers to improve competitiveness and performance.

We will, of course, need to ensure that our provider base meets the demands of this new environment. We will also need to build contracting and relationship management tools and processes that can deliver levels of performance and value far beyond those achieved today, and Chapters 2 through to 9 of this book will give you some insight into the latest thinking in these dimensions. However, ultimate success will be driven by outstanding strategy and decision-making – Chapter 1 will help you begin your journey.