

## Q&amp;A

# Chiltern to the core

**GLENN KERKHOF, CEO of the global CRO, talks about the growth of Chiltern and its strategies for the future**



**Q** It's been an exciting time for Chiltern since it was acquired in July 2006. What has the effect been on the company?

**A** We have really focused on providing a well-balanced global structure and suite of services. We have introduced some new leadership, strengthened global systems and processes and focused the business on our core clinical development strengths. Our staff have enthusiastically embraced these changes and are focused on building a clinical CRO that continues to be rigorous in its approach but is also flexible and a pleasure to work with for customers and staff alike. The effect of these changes has been rapid growth in sales and demand for our services. We've really had a great time and our customers are responding very well to the positive changes we have made.

**Q** How are you expanding the business?

**A** By acquisition and organic growth. In October we announced the acquisition of CTMS Inc based in Bristol, Tennessee. CTMS brings a wealth of therapeutic, operational and management expertise, together with very strong client relationships. The acquisition has allowed Chiltern to double its presence in the US and provides a strong platform for further development of our services and brand. CTMS' and Chiltern's US operations will be fully integrated by February 2008 under the Chiltern brand and under the leadership of John Vann, a founder and the CEO of CTMS. John will be a very important part of the global management group going forward and will continue to strengthen and grow our clinical operations in the Americas. In CTMS we have found a very like-minded organisation and together, while not being the biggest CRO, we believe that we will be one of the most attractive to clients.

In parallel with the CTMS acquisition we are making plans to establish further operations in Russia, Eastern and Central Europe and my home country, Australia. We will also take a look at Asia and Latin America during 2008.

Chiltern now has over 1,100 staff globally with 35%

of our staff based in the US and the remainder in Europe and India. We think this is a nice balance.

**Q** What services are you looking to develop in the immediate future?

**A** We are very strong in our core Global Clinical Development and Resourcing Solutions operations (providing teams for outsourced trials or insourced staff directly to our clients; sometimes providing a hybrid of the two). Of particular interest now is the further development of our early- and late-phase operations. We have a Phase I presence in the UK but we would like to supplement this with another high-quality unit. In late-phase, where we already have some very good people but have been light in the US, we have recently recruited Steve Albrecht, a well-known US late-phase specialist to refine our service offering and build our portfolio of work there. We are seeing an encouraging response to this from our clients.

One further area to mention is Biometrics and EDC, which is led globally for Chiltern by Dr Jim Esinhart. Last year we announced EDC alliances with ClinPhone and Medidata. We are rolling these systems out as our internal global data management solutions in addition to having the capability to support sponsor databases with our internal teams and systems. Again, this level of flexibility is key and a significant step to making our Biometrics function a competitive strength for Chiltern globally. Today for example, we are helping two top ten pharmaceutical companies with their global EDC implementation internally and at investigator sites. We expect to see continued growth and development in this area.

**Q** What made you decide to specifically focus on late-phase trials?

**A** To be clear, all aspects of clinical trials are important to us. But late-phase is a special focus because we see our clients entering an era of stricter supervision by the regulatory authorities and

increasing demand for specialised services during the post-submission and post-approval period. According to the FDA, the number of clinical studies has risen on average by nearly 7% per annum in the past six years, but there has not been a corresponding rise in the number of approvals. This trend suggests more late-phase clinical trials, periapproval studies and patient registries are being performed. These programmes present a unique set of challenges compared to traditional Phase II/III trials and require specialised processes and technology. Today, our staff are focused on meeting these challenges and we are increasing our capacity as demand grows.

**Q How does Chiltern see itself in the CRO market?**

**A** We see ourselves as an emerging, competent and reliable mid-sized provider that is focused on relationships, service delivery and quality. We see both pharmaceutical and biotechnology companies looking for more provider options – alternatives to the five largest clinical CROs if you like. By virtue of our size we can still be flexible and responsive yet match or exceed the quality and delivery standards of our major competitors. Our senior management team are readily available to our staff and customers and we see this as key to our future development. Establishing strong, practical, accessible and trusting working relationships with our clients (and staff) is fundamental to Chiltern.

**Q So you don't see strategic outsourcing and preferred-provider agreements as the Holy Grail for every CRO?**

**A** Without a doubt every CRO wants to hold a number of preferred-provider agreements and investigate and establish more strategic relationships with sponsors. Chiltern is no exception here. But we have always done well also from the simpler 'repeat business' style that some sponsors prefer. And we don't see anything wrong with that – in fact we think it's very acceptable to hold a portfolio of different kinds of arrangements with our clients and a spread of relationships so our dependence on any one client is not too great.

**Q What would you say sets Chiltern apart from other CROs in your field?**

**A** A CRO is a dynamic linking of process, system, network – let's call this infrastructure – with people, know-how, control and focus – let's call that application. The infrastructure and the application are caught up in a continual review and improvement process as we seek to deliver projects more rapidly, more competitively priced and more effectively.

We see many areas where Chiltern has and can take advantage within both our infrastructure and our

application. Some of these advantages will be visible to our sponsors in a practical way, such as the delivery of experienced and well-supported project teams and some will be more internally accessible like better processes, access to information and shared experiences.

But if I had to boil it down to a single ingredient I would point to our *people* and our recent successes are testament to that. Our people are knowledgeable, responsive, communicative and focused. And we work hard to keep it this way through our recruitment, training and review programmes and of course the infrastructure we provide for people to work with. Our people enjoy working at Chiltern because they are well-supported and it's a friendly and productive environment.

**Q How do you see partnerships between the pharmaceutical industry and CROs developing?**

**A** I think guidance to this question can be found in considering the macro trends of the industry. First there is growth and secondly there is a need to be more productive. All of this points to greater outsourcing to CROs such as Chiltern, but as your question implies, also new modes of working together. We find this very exciting.

But first let me repeat that we believe the simpler 'spot' and 'repeat purchase' relationships are here to stay and we continue to value them as an important part of our work portfolio. However we do see a greater opportunity than ever before to collaborate beyond this level. And here we think the answer lies in the level of integration between sponsor and CRO. This greater integration may take the form of, for example, CRO-embedded teams within sponsor operations, targeted sponsor-specific study design and startup arrangements, or of course some structured departures from pure fee-for-service arrangements. The building blocks for this greater integration are, consistent with my answers to earlier questions, establishing trust, understanding and confidence between client and provider. And this for us and I think the industry as a whole is a major focus.

**Q What would you consider the single most important challenge currently facing CROs generally and Chiltern in particular?**

**A** I think there are immediate and strategic challenges that CROs need to be focused on. In the short term, the industry needs to be able to maintain quality but cope with the growth demands placed on it. Largely, for us at least, this boils down to being able to attract and recruit the right people in the right place at the right time. But in the longer term, the challenge goes back to the question of how to support pharma/biotech productivity through optimal sponsor/CRO linkages.