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Alastair Devlin discusses the concept of virtual pharma companies

Interviewed by Rebecca N. Lawrence

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What was the reason behind the launch of Fulcrum Pharma?
Fulcrum Pharma was launched in August 1999 but for 4 years, it had been Protodigm Ltd, a wholly owned subsidiary of Hoffman-la-Roche (Basel, Switzerland). This company did the same as we are doing now except that we carried out the work only for Hoffman-la-Roche, whereas as Fulcrum, we now do work for many clients.

Protodigm was set up as an initiative by Roche to see if using a virtual model of development (i.e. using entirely external resources) was a cost-effective and rapid way of developing their products. Our company was set up and given three products to develop and Roche set benchmarks of time and cost. Protodigm was then launched formally in September 1996. Roche closed Protodigm in 1999 and the management then formally opened Fulcrum with the same people and facilities. This was made easier by the fact that when we started as Fulcrum, we had the legacy business from Roche plus we already had new pieces of work. However, we raised extra capital on the Stock Exchange.

Exactly what does the company do and in what way is it virtual?
We do drug development on behalf of clients, including designing the development plans and programmes, and the strategy aspects. We then assemble teams made up of different contractor companies [for example, contract research organizations (CRO) and contract manufacturers] that execute the development activities under our management. Our development team does the same as a project team inside a pharma company except that, in our case, the individual members of the team come from different companies.

What advantages do you feel it offers both the company and the customer by being 'virtual'?
There are a number of advantages of this method. One of the greatest advantages for our clients is that it does not consume any internal resources and therefore does not participate in the company's overheads because they do not have to develop an infrastructure. The main general advantage of the model in its own right is that we are free to select the best fit of contractors and people for each individual project. Within a pharma company, they already have their staff and resource base and they therefore would have to pick from this or from a single CRO. In our virtual model, we are free to select the best individual skills from a large number of organizations and blend them together for each individual project.

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How does the model enable decreased drug development costs and reduced cost and time to yes/no decisions?
The reduction of cost comes first of all because the money is not coming from an internal resource so the client does not have to build up a permanent headcount or the infrastructure to support it. The other saving is that the programmes are designed to be very cost-effective through the complete freedom of resources available for us to choose from.

We can also put together a programme that is time-efficient. Each project team is essentially its own organization so that the decision-making process is fast and flexible and programmes have low inertia so that they can rapidly respond in real time to observations made during development.

Does the project team involve someone from the customer?
It varies: some want quite close involvement and others really very little involvement. It really depends on their choice and we are very happy to work both ways.

Who puts the advisory board together?
We put together an advisory board for each individual project. Obviously, if we are coming into a development at a later stage and the customer already has an advisory board assembled, then we work with that board.

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How do you think pharmacogenomics will impact the work the company does?
We have already included pharmacogenomic aspects into some of the planning we have done. I think, if anything, it presents an opportunity, as development becomes more focussed it will provide more potential for our model as we can put together small focussed teams and run them very quickly. Obviously, if pharmacogenomics reduces the target populations per drug, then speed and cost become even more important.

What have been the key developments of the company so far?
Landmarks in the company's existence include our flotation on the stockmarket, which changed the nature of the company and supported our recruitment policy. We set very high recruitment standards and typically we recruit staff for operational management roles who would normally be in senior managerial levels. To motivate this type of person and to recruit them, we felt it was important to be able to offer ownership of the company with an equity position, and we now have 12 members of the company.

Another milestone was opening our office in Japan in January 2000. Japan is an extremely important market for us and we

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have been pleased with the progress of our Japanese office. The other main landmark for us is that, at the end of our first trading year, we made a small profit, which is unusual for a start-up.

What is the main obstacle you have found to this new idea taking off?
There have been no specific obstacles. It is a new way of doing development so we are expending a lot of time explaining the model to potential customers so that they become comfortable with it. However, this is just the natural evolution of any new form of business.

I think we probably get as many different concerns as we have different customers. They all have their own perspective of drug development and so they address specific questions to us on how we would deal with certain situations.

If you could set up the company again, what would you do differently?
Do it sooner!

Do you expect other similar companies to follow and are there any others that you know of?
I would be surprised if others did not follow as it has certainly been a successful model in our hands. There are occasional names that appear and disappear who might be doing something similar, and there are some groups that offer maybe segments of what we do, but we are not aware of anyone else who currently offers the whole range that we do.

What are the future goals of Fulcrum Pharma?
To grow the business we are in. We are still less than 2 years old as an independent company so we are still very much at the bottom end of our growth curve but it is turning up quite nicely. We are just working hard to maintain that growth but basically offering the same service to an increased number of customers.

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Molecular biology databases: today and tomorrow

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Biological scientists today can no longer afford to ignore the Internet. Whether it is used to find research funding, collaborators, current articles, data or data analysis tools, it has changed the way we work and is not a passing fad. The Internet's molecular biology research data has grown prodigiously over the past two decades. For example, GenBank began with fewer than 10^3 sequences in 1982 and had over 10^7 sequences by the end of 2000; its current doubling time is less than one year [National Center for Biotechnology Information (NCBI) (2001) GenBank statistics, http://www.ncbi.nlm.nih.gov/Genbank/genbankstats.html].

GenBank, and many other web-based databases for molecular biology, are interlinked and freely available to the scientific community. Those mentioned in the text are listed in Table 1. Access to them is as important to scientific progress today as is access to a laboratory or library. But few understand how public research databases develop and are maintained. Their future is not assured.

Brief history

From the first dawn of today's now-vigorous field of bioinformatics, protein sequence information was assembled into databases and made freely available. In the 1960s and 1970s Margaret Dayhoff's pioneering work on protein evolution led to the distribution of the Protein Sequence Database, now more familiar as the international Protein Information Resource (PIR)[1]. In the early 1980s, this inspired the first public releases of Amos Bairoch's SWISS-PROT sequence database[2]. Then the first nucleic acid sequence databases began to proliferate, and ultimately to cooperate, in order to cope with the increasing quantities of sequence data being generated worldwide (e.g. GenBank[3], EMBL[4], DDBJ[5]).

At that time, there was no question that making the data freely available was both desirable and necessary, to help the research community as a whole make the best use of the data, to facilitate innovation, and to accelerate discovery. Indeed, by 1995, the European Molecular Biology Laboratory had established the European Bioinformatics Institute (EBI). Its mission was, and remains, to 'ensure that the growing body of information from molecular biology and genome research is placed in the public domain and is accessible freely to all facets of the scientific community in ways that promote scientific progress' [EBI (2001)

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