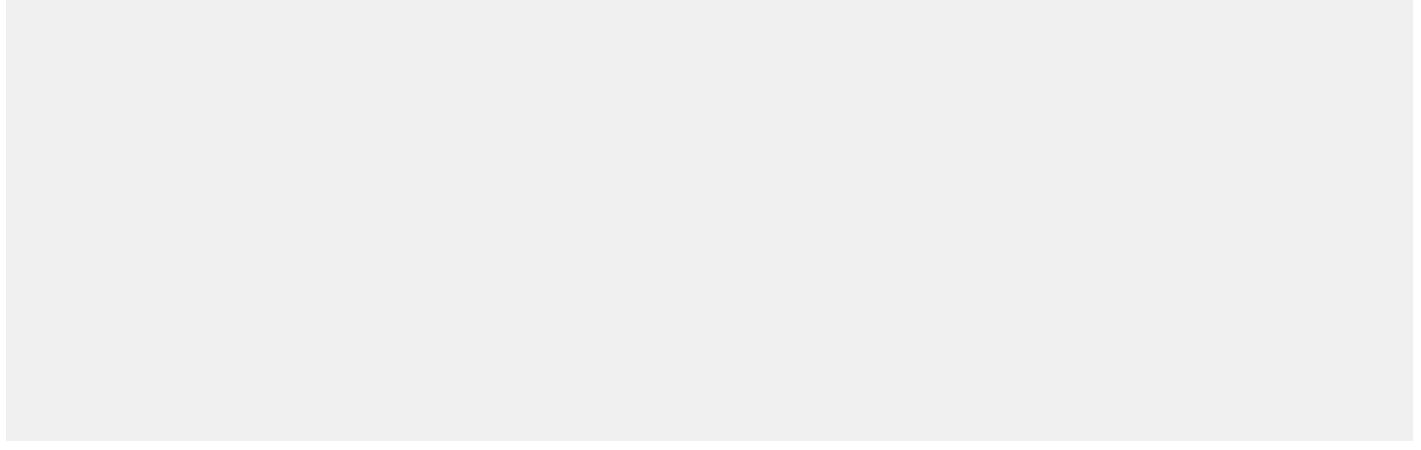


Interview with Helen Allars and John Edington, Managing Director and CEO, Datapharm Australia Pty Ltd



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The Australian pharmaceutical sector has seen recent innovations through PBS reform and various working groups shaping the future of the industry. Can you comment on how Datapharm is reacting to these opportunities?

Datapharm has actually put in a submission to the review of the National Innovation System, highlighting that innovation is of paramount importance and that the Australian government needs to maintain and encourage innovation. This applies particularly to Australian biotechnology companies, many of whom are clients of Datapharm Australia, and for whom we look after clinical research, as many are small and are in particular need of help in this regard. The industry needs the initiatives similar to the Commercial Ready grants and P3, which are important if innovation is to continue. Companies need venture capital and other forms of fund raising as well as government encouragement to help them perform clinical research. Datapharm Australia is supporting these companies, as a research service provider. There seems to be a strong opinion throughout the industry that one of its main problems is a lack of funding, not only from government but from Venture Capital and Private Equity, due to Australia's geographical isolation from West Coast US or Europe.

In your opinion, should it be the government's role to directly help the small biotechs?

Absolutely, we see it as an important government role to help the small biotechs. Datapharm itself benefits from some government funding under the Export Market Development Grant, which allows our company to sell Australian expertise to sponsors in America and Europe. Our marketing at overseas conferences, brings clinical trials to Australia. This government funding is helpful for us, and also for small biotechs that need support to help perform clinical research. In terms of direct investment in the company, that may be a different issue for angel investors, VC, or PE as you mention, but in terms of research the government should continue to help with R&D which it does to some extent through tax concessions. In your submission to the NIS review, you stated concerns regarding the government support of public research organizations performing similar tasks to Datapharm in Australia.

Can you clarify this position for our readers?

The Federal Government, and especially some State Governments, put money into public “not for profit” research institutions associated with universities and hospitals, and then those groups compete with privately run research organisations such as Datapharm. There are numerous reasons why this can potentially pose problems. It’s not just an issue that they’re competing to service research, but also that they may not always be familiar with how to conduct the work correctly according to international guidelines. The small biotech companies using our services don’t usually know much about doing work in technical compliance with international guidelines of GCP so they rely on our expertise in this respect which can save large amounts of investment capital from being poorly used.

Can you speak to why a small biotech company would choose Datapharm over a larger or publicly-funded organization?

Datapharm Australia has a very well respected record of quality work because of the love of the science and enthusiasm to make all projects successful . Over 20 years there have been many accolades and word of mouth recommendations. Usually there are “Requests for Proposals” (tenders) for clinical trial work, and often there is a high priority on cost, but experience is another aspect our clients appreciate when working with Datapharm Australia. We value relationships and partnering with our clients, and provide appropriate advice and training whenever necessary. When Sponsors deal with a government or semi-government organization, they may not necessarily know how the work is to be done or to what standard. Datapharm also has a very talented pool of people, including PhDs and post-docs , medicos, with most having master’s or higher degrees. They are dedicated solely to Datapharm and its clients’ work. Some university or government groups may have overworked & detached professors with little time for clinical research, due to teaching, conferences & management commitments.

Datapharm provides a variety of clinical trial services, including all aspects from protocol development, investigator selection to the statistics & study report can you break down the company's focus?

When the clinical trial is ongoing, all those areas must be addressed. Monitoring is like an auditing role, and complements data management, statistics, medical writing, audit trail, and validated EDC systems, which are all done to international standards.

Datapharm's focus is quite niche in all those areas, providing full service across them, while other local companies may not have some services as well developed Why is Australia a globally excellent place to perform clinical research?

Australia has a history of very talented medical doctors doing research, some of whom have won Nobel Prizes, a strong regulatory system, and hotspots in various therapeutic areas like melanoma, asthma, and seasonal allergy. Many Australian doctors are trained in Good Clinical Practice and know the ropes for doing trials. Comparatively, Australia has a good regulatory system in terms of quick approval times: for example a Sponsor who chooses to go to Australia rather than China, will have their clinical trial approved through the CTN system in 4-6 weeks compared to 9-12 months in China. When the Baume Report came out and reformed the regulatory system, it was really good for Australia, and represents an advantage for the country. We are hoping that attempts to harmonise will not change the speed of our regulatory system. In the past, Australia also had a big advantage due to favourable exchange rates, especially for European and American Sponsors, but some of this advantage has evaporated, with Australia now approximately 20% less expensive than America, although still significantly cheaper than Europe. American companies, however, are still strongly attracted by a number of excellent phase 1 units located in Australia that conduct many of the early phase biotechnology studies.

Can you speak to the importance of local expertise and knowledge, as Australia's oldest CRO?

Datapharm Australia's local knowledge of sites and expertise spans 21 years and is attractive for overseas companies wanting to do or to extend their clinical trials in Australia. Where an American company wants to do a melanoma study in Australia, they're better off using a local CRO like Datapharm, that knows a lot of the sites and the best way to go about doing trials. Datapharm has supported the training of site study coordinators around Australia and New Zealand for the last seven years. This local connection becomes an advantage in completing the work successfully.

Which major milestones or achievements would you like to highlight in Datapharm's recent history?

Datapharm just finished a very big arthritis study with an overseas client involving 11 sites, and started another study in a very interesting therapeutic area for the affiliate of an overseas company, with 10 sites. These were set up very quickly and efficiently. Datapharm found the sites, did all the ethics applications, and has coordinated the whole project, including the data management. Datapharm is helping with recruitment for the study, managing a 1-800 number call centre for patients to dial in. This is all backed up, of course, by a good in-house statistics team, allowing Datapharm to perform the analysis closely with our medical writing team of PhD and medically qualified scientists who write, the final study reports in-house thus saving time and ensuring quality. The company keeps on top of technology, with electronic data capture and a developed web portal for putting documents in a secure environment and tracking changes, where people working in different countries and states can exchange documents and data files in a safe environment. This also allows clients to upload data files collected from an electronic system for a data safety monitoring board committee, and the code can be put in on a separate place, with separate securities, and Datapharm's statisticians can have secure access to allow analysis of the files. The company has also an administered web portal service, and tracks documents in a trial masterfile, with some really innovative systems, all underscoring Datapharm's commitment to the highest security standards.

In such a tight labour market, where does Datapharm search to fill out its team?

It is very difficult to find the talented people in Australia who have the right training. Some of our competitors are resorting to bringing in people from overseas to fill in the gaps. Fortunately, Datapharm has a lot of longevity and finds that people like working with us once they join us. Consequently we do not have a high turnover. The company is family-friendly, with flexible hours to accommodate varying needs, adapting packages to suit educational or family pursuits. However we are always on the lookout for new recruits, especially experienced biostatisticians. Datapharm upgraded its Queensland office at the end of 2007 in response to the expanding workload, and has another in Melbourne, where Datapharm has a lot of clients.

Does Datapharm usually train in-house, or rely on already acquired expertise from outside laboratories or universities?

Datapharm has done a lot of training in-house, taking many PhDs and post-docs who are keen to enter the industry from the start as Clinical Trials Assistant (CTA) and working up to Clinical Research Associates (CRA), sending them to courses and learning on the job, and very soon they're up and running.

In the future, what can we expect from Datapharm in terms of overseas presence?

Datapharm currently markets at overseas conferences, and for the past few years, has attracted work from overseas companies to Australia. Datapharm has been part of a network of CROs and is

now developing its own CRO network to work with overseas firms, because there are Australian clients sending work overseas who are up to phase 2 and 3, who want help in managing their trials in the US or Europe. Datapharm is currently hoping to start a trial for a new and innovative surgical device, which may be run in Australia, India, Europe, America, and Poland, where Datapharm has networks of people running those trials for us. We've also got an auditor on board who is our quality manager and is auditing trials in Asia, and that's been an interesting process to educate ourselves in how CROs and sites in other countries work. In the future, Datapharm's growth will be external, but at the moment the majority of clients are Australian, 60% of which are biotech. Big pharma is now mostly involved in Datapharm providing services for phase 4, post-marketing level, and observational studies, while the biotechs are requiring help on phase I,II & III studies.

With all this potential growth in the future, where do you want to bring the company in the next five to 10 years, and what would be the biggest differences to notice?

Datapharm is undergoing a major organizational change to allow modest growth, while maintaining our quality and caring culture, which is what we want to do. In our Sydney headquarters, our construction of a new additional office building to accommodate up to 20 personnel has offset the timing of a move to a larger space, which we may need eventually. Datapharm was very mindful the world's economy was becoming heated, and arranged early for its current contracts to be kept cashflow positive in the upcoming years. This will ensure financial stability and for Datapharm to be economically attractive to clients. Overall, future growth will be underpinned by our sound management systems, so that we always know how we're going, and what we need to service our clients.

What is your final message to Pharmaceutical Executive readers about Datapharm's activities and growth perspectives?

Datapharm is a friendly, and family-friendly, organization. We don't want people to be overstressed, because they don't think or work as well under stress. In the future, Datapharm's course has two options. One is to move out and grow on our own, and the other is to move out and grow with somebody else. But the company is certainly not staying still, and has young people here keen to move forward, although we don't necessarily want to develop an American style of rushing into growth. This can compromise quality and a loss of the valuable founding culture. We are different, because we think carefully. Datapharm likes to grow with its clients, particularly with the Australian companies. We like to be in at the front end with how they're planning projects, and work with them to be successful as well. Our input to their organization is to make them successful on the technical and developmental sides, which is what we like to be excited about. Rather than being a speedy corporate growth vehicle, Datapharm is still very much about the science, and enjoys the innovation side of things.

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