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ASIA EDITION

Strong clinical trial infrastructure puts Australia in a strong position

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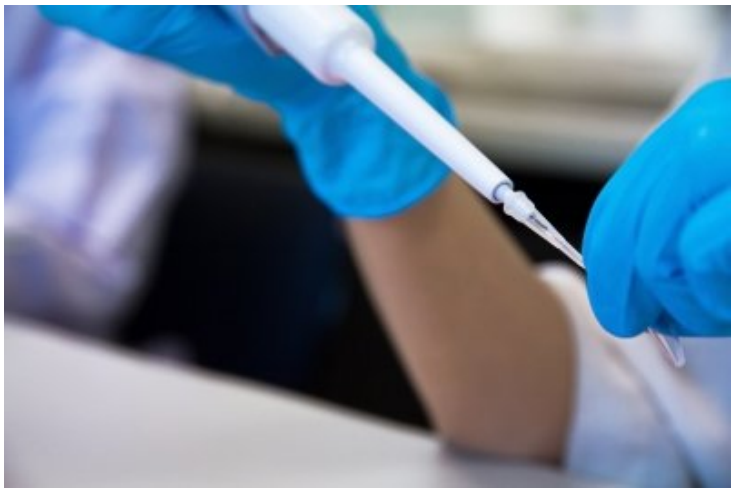

by **Luke Edington**

Mr Luke Edington is the clinical project manager at Datapharm, Australia. He has experience in managing projects with an eclectic mix of clients and therapeutic areas.

Australia's strong history of quality and experience in clinical research is well known, and whilst being a comparatively mature market, Australia is a young country whose clinical research sector continues to grow and adapt to the globally competitive climate of the day. Needless to say, there remain many great opportunities for those seeking to undertake research for product development. With the global financial crisis fallout still under way, and an understated reduction in investment in clinical trials, service providers and innovators alike are becoming more astute in allocation of their limited resources.

Does the possibility of up to 45 percent tax refund of eligible expenses on your next clinical trial sound too good to be true? Well it might be, but whoever dared in Australia, has often won. Mesoblast recently announced receipt of $4.3 million from the Australian Tax Office under the Federal Government R&D Tax incentive program, indicating that this related to expenditure in the period 2011-12. These funds would be used to advance development of its mesenchymal precursor cell technology platform and product pipeline. The program is also of interest to foreign entities seeking to conduct clinical trials through a local Australian subsidiary or sister company depending upon eligibility.

There is anecdotal evidence that some Australian companies are also benefiting from this incentive outside Australia. There is an increasing desire from most Australian Universities to 'engage' more with the 'industry'. Historically, at least in Australia, universities have been very insular from the commercial world, especially with regards to research projects. This remains the case to a point, However, things seem to be changing albeit slowly. Changes in grant funding programs, which in some cases now look favorably to applications that include an 'industry' or a commercial involvement may have spurred this trend.

Perhaps with increased competition for student enrollment (especially from overseas) to offer paths into the workforce or at least differentiate the educational product. Another thought is that there may be a desire to compete with industry service providers, or at least for universities to start to become more entrepreneurial. Intellectual property (IP) generated in the university environment can be leveraged on and be gained from. New South Innovations for the University of New South Wales (UNSW) has opened up its doors to their easy access or "Free IP".

Datapharm recently successfully assisted a first-in-man clinical trial in conjunction with UNSW, which was successfully published in The Lancet earlier this year. Some larger clinical research organizations (CROs) are closing down their data management operations in Australia and many are moving offshore to Asia in order to benefit from highly qualified workforce available on low wages. Datapharm is now one of the last remaining CROs in Australia with complete data management and statistics option offerings inhouse for clients. In terms of growth in other markets, some local CROs are trying to penetrate other Asian markets on their own, or with the help of investors, whereas companies like Datapharm are partnering with other locally-based CROs globally through their Dai-Sys consortium to offer international clinical trial services to clients.

With a diverse multicultural population, Australia is well placed to provide studies targeting specific demographics. The Australian government has a commitment to maintain the country's international competitiveness when it comes to clinical trials, and have recently committed $9.9 million to this cause. Also, Australia is lucky to have such an efficient regulatory system.

Current challenges relate to the research governance review process for Australian public hospital projects in a number of states, which has added to timelines and cost, despite initial intentions to speed up processes through multi-center study single ethical review system. The trouble is that this is an issue under the state's regulations, so federal money may not be able to achieve its aim here. Besides, Australia remains internationally competitive with regards to set up timelines for clinical trials. Another important part of the federal program, which is currently under way, is review of clinical trial costs. There is an aim to have more streamlined or transparent cost systems for clinical trial fees charged by investigator sites. The cost system is not to be considered a price fixing approach, but rather a basis for discussion.