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ASIA EDITION

Australia is the new hotspot for clinical research

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As everyone already knows, the international pharmaceutical industry is currently undergoing a number of significant changes brought on by pressures caused by the weakening financial situation in the US and Europe.

Big pharma are continually being forced to streamline their operations by narrowing their focus and specializing on one or two main areas. They are also deciding to cut costs at all points along the concept-to-market chain by opting to outsource virtually all of their development processes. Despite the considerable pressures on the industry, Australia is well positioned to emerge as the new 'hot spot' for clinical research due to two important factors.

Unlike other parts of the world the Australian therapeutic product development environment has always been relatively cash starved, and therefore well versed with restricted budgets, and outsourcing services to CROs and other niche services providers in order to develop their products and to move them along the development pipeline. So this "paradigm shift" that is taking place in other regions is for Australia, merely an alignment to the offering (and strengths) of its product development pipeline.

Coupled with a favourable clinical research environment, and the Australian regulatory system, which is headed by the robust yet relatively simple Clinical Trial Notification (CTN) Scheme, Australia becomes a key option for global product development. This becomes exceptionally evident when compared to the US Investigational New Drug (IND) and EU Clinical Trial Application (CTA) procedures. The CTN has enabled Australia to become increasingly attractive to time and money-sensitive

sponsors and their financial backers, eager to generate timely, reliable and cost-effective early proof-of-principle clinical trial data. The efficient regulatory approval process also enables companies to commence trials in weeks, rather than months.

Now, with the advent of the R&D Tax Credit Scheme, that enables eligible applicants to receive a 45 percent reimbursement of R&D expenditure, Australia is an even more attractive option.

The Australian Government and state governments (such as Queensland) have continued to invest billions of dollars over the past decade to build and improve world class research and medical facilities and infrastructure. Many exciting and important initiatives have been established, bringing together world class centers in order to link translational health researchers, close infrastructure gaps, provide facilitated pathways for translational research in critical areas, support the funding of critical research and focus on international engagement.

Therapeutic Innovation Australia (TIA) was established in order to achieve these goals and increase the efficiency of Australian translational research. The TIA-Queensland Node is a consortium of five highly respected pre-clinical and clinical translational research centers with complementary expertise and experience.

The TIA-Queensland Node comprises of the following centers, including University of Queensland Center for Intergrated Preclinical Drug Development (CIPDD), University of Queensland Diamantina Institute, Griffith Health Institute (Griffith University), University of Queensland Center for Clinical Research-Center for Clinical Diagnostics, and the Queensland Clinical Trials and Biostatistics Center (University of Queensland). Australia's collaborative nature and eagerness to continually enhance the country's research capability and capacity, professionalism and international regard add to the country's appeal.

Australia plays home to a multitude of talented and respected local and international scientists, highly regarded research facilities and its universities are some of the highest-ranked in the world. Queensland in particular, has an international reputation for its clinical trial expertise including pre-clinical and early clinical phase development work, pharmacokinetics and pharmacogenomics.

State-of-the-art medical research facilities and hospitals, a globally active industry association like the LSQ, an environment that stimulates clinical trial professionalism and co-operation, and adherence to national and international ethical, quality and regulatory standards, make Queensland a prime choice for national and international sponsors who are wishing to conduct clinical and pre-clinical trials.

Furthermore, as we enter the 'Asian-Era', Australia's geographic location within the Asia Pacific region provides the country with a great advantage. Australia's proximity to the rapidly growing South East Asian markets and existing close trading ties with many Asian countries, enable Australia to provide great opportunities for international pharmaceutical and biotechnology companies, and research institutes.

With the improving infrastructure, medical and research expertise as well as increased government and industry interest and funding moving towards medical research in the Asian region, Australia is well placed to take advantage of this change in global interest and attraction towards Asia, and provide international stakeholders with a safe, professional and cost-effective stepping stone in to the Asian growth markets.