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Australia to get independent clinical trial regulatory authority

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Australia, often regarded by market experts as the most mature clinical research market in Asia Pacific, has leveraged substantially on the recent boom in the global life science industry. Although Australia shot to fame as a research hotspot in the early part of the last decade, its evolving and effective regulatory system has helped the country retain its position on the global chart of leading clinical research hubs.

In recent times, however, a few reports of misconduct in Australian research have emerged. Allegations of inaccuracies in reporting of research results became a burning issue after a review was published in the *Proceedings of the National Academy of Science* in 2012. The review by Dr Arturo Casadevall from the Albert Einstein College of Medicine in New York, US, showed that the percentage of scientific papers that have been retracted or withdrawn by the authors because of mistakes had increased 10-fold in the last three decades. He also found that out of 2,000 retracted scientific papers, 20 percent of mistakes were genuine errors, while almost 70 percent of the errors were due to misconduct and suspected fraud.

Clinical trials of an experimental cancer drug being undertaken by the University of New South Wales were suspended after questions about the accuracy of some preliminary results were made public. Further allegations of inaccuracies stemmed out of a research result from the Queensland University of Technology. In both instances, the scientific publications were retracted. Following reports of similar cases, a clinical trial of a skin cancer drug was suspended in 2013, leading to a unified call from the industry for an independent body to oversee scientific research in the country. Australia's current rate of investment in research and innovation is 2.2 percent, which is considered below average for an OECD country and lags behind regional competitors such as Korea and Japan. However, recent developments highlight that there is hope on the horizon.

Industry boosting endeavors

Ahead of the elections in August this year, Australian Prime Minister Kevin Rudd announced the unveiling of $125 million fund for health and medical research, focusing on regenerative medicine. The scheme is aimed at taking Australian breakthroughs from the lab to the patient and the government funding will be matched by the private sector, bringing the total research fund to $250 million. "In the 21st century, the next frontier for medicine will be biological medicine, regenerative medicine and genomics. Australia has a track record of great medical breakthroughs and extra funding would bring more jobs

and other economic benefits to Australia. The government estimated that between 2009 and 2020, the financial burden of end-stage kidney disease would be $12 billion, so this funding targets kidney research in specific," the Prime Minister had said. This announcement came after the McKeon review of health and medical research released 21 recommendations for better health results in April this year.

Australia has provided international stakeholders with a safe, professional and cost-effective stepping stone in to the Asian growth markets.

International standards of conduct for clinical trials, developed by the International Conference on Harmonisation (ICH) and the International Organization for Standardization (ISO), provide a benchmark of clinical research quality. Also, the ICH or ISO good clinical practice (GCP) standards are mandatory for all Australian clinical trials, which involve unapproved medicines or medical devices. The regulations in the country currently revolve around a simple Clinical Trial Notification (CTN) scheme administered by the Therapeutic Goods Administration (TGA), which has helped in obtaining approvals within weeks. Under this scheme, research proposals are submitted directly to the Australian Human Research Ethics Committees (HRECs).

The committee assumes primary review responsibility for ethical and scientific review. The TGA also administers the Clinical Trials Exemption (CTX) scheme, under which proposals are submitted to the TGA for scientific review followed by ethical review conducted by the HREC.

Australia has also developed ethics review processes for multi-center research in order to help reduce unnecessary duplication of review of research. Furthermore, the tax credit scheme has attracted many, as it allows eligible applicants to receive a 45 percent reimbursement of research and development expenditure. Well-defined regulations, swift and efficient procedures, advanced infrastructure, cost efficiency, and strategic geographical location have all added to Australia's popularity as a research hub. The country has close trading ties with many Asian countries and is in close proximity of the expanding South East Asian markets too. Further, the fact that the Northern and Southern hemisphere seasons are reversed also provides an advantage when conducting trials here.

The paradigm is now shifting towards conduction of priority-driven research and the system is aiming towards capacity building to create an economically sustainable healthcare system. Australia's agenda for the coming years is to improve the research integrity by establishing an independent regulator and create a reward system for early and public self-disclosure of errors. The system will also aim at creating a punishment for intentional or reckless misconduct after active independent investigation of allegations.