

EDITORIAL

Australia's Only Commercial Independent Institutional Biosafety Committee

Queensland Clinical Trials Network Inc. (QCTN) attracts and encourages world class, leading edge, first-in-man therapeutic research that draws the attention of some of the world's brightest minds to Australia. For this very reason they identified the need for, and formed, Australia's first Independent Institutional Biosafety Committee (IBC).

The IBC was brainstormed with members when they were working together to establish a trial to investigate a genetically modified organism (GMO). The member organisations approached QCTN, whose role it is to facilitate clinical trial activity, and to initiate the removal of commercial barriers for the benefit of industry stakeholders, members, sponsors and ultimately patients who benefit from the introduction of cutting-edge therapies.

QCTN acted immediately to establish its new IBC thereby increasing its members' ability to assist local and international organisations needing to conduct clinical trials of GMOs in Australia.

'This duly established committee has been formed after QCTN recognised the need to ensure that this important piece of infrastructure existed,' QCTN CEO Mario Pennisi recently stated.

'This IBC meets regularly to review submissions and, coupled with the soon to be established HREC (Ethics Committee), means that a one stop efficient review service can be provided to members and their clients here in Australia,' he continued.

The role of the IBC at QCTN is:

- To review the applications to administer GMOs to human volunteers as part of authorised clinical trials in Australia (as exempted or notified under the *Therapeutic Goods Act, 1989*).
- To support pharmaceutical/biotechnology companies with commercial distribution licence applications (DNIR or DIR) at the discretion of the QCTN and IBC.

The three QCTN members who first identified the need for an Independent IBC have a history of high level collaboration offering a 'seamless' service and were also the first organisations to realise commercial benefit from the establishment of the new committee.

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Dianne Jackson-Matthews, Director of Regulatory Affairs for ERA Australia commented 'The intrinsic value of the QCTN IBC is its independence - the fact that it is not associated with, or dependant for its activities on, any specific research institute or hospital. Committees with such affiliations are often committed to restraining their efforts towards internal projects and responsibilities, which tend to restrict the range of projects that an IBC can review. Therefore they are not necessarily accessible to the biopharmaceuticals industry in general.'

The legislation regulates 'dealings' involving GMOs (which includes clinical trials involving GMOs). Persons or organisations planning any undertakings that involve GMOs need to apply to the Office of the Gene Technology Regulator (OGTR) through an accredited IBC, to obtain approval to undertake work with GMOs.

Professor Tony Webber of Clinical Network Services added 'Increasingly, protocols being presented to us involve GM products and having an independent IBC makes it easier for the CRO and the sponsors to get the work done. The fact that this committee has been established is testament to QCTN's responsiveness and recognition of its members' commercial needs.'

The QCTN IBC is constituted and functions as per the requirements of the *Gene Technology Act 2000* (Cth) and the *Gene Technology Regulations Act 2001* (Cth). Collaborating organisations must also refer to the 'Handbook on the Regulation of Gene Technology in Australia', published by the OGTR, to obtain information about the requirements of the legislative scheme.

Mark Reid, the Bioregulatory Consultant who coordinated the development of the QCTN IBC commented "I was approached to coordinate this initiative and have subsequently joined QCTN. The companies involved are visionary and we have collaborated to develop an innovative, industry first model for GMO therapeutic evaluation with the QCTN IBC".

The IBC is responsible to the QCTN for ensuring that the requirements of the legislation are met. The IBC is also responsible for providing advice and assistance to collaborating organisations wishing to undertake work involving GMOs.

By late 2007, QCTN will also operate an independent Human Research Ethics Committee (HREC). Working both of these committees in tandem will further assist sponsors in undertaking time and cost-efficient clinical research in Australia.

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Australian Regulatory System Overview

Therapeutic goods

There are two Australian federal government bodies controlling therapeutic goods regulation – the Therapeutic Goods Administration (TGA), in the Australian Government's Department of Health and Ageing, and the National Health and Medical Research Council (NHMRC). The TGA is the national therapeutic regulatory authority, whilst the NHMRC is responsible for:

- allocating Commonwealth funds for health and medical research
- considering ethical health issues and
- regulating sensitive medical research activities.

In this capacity, the NHMRC provide the National Statement on Ethical Conduct in Human Research. The National Statement is Australia's primary source of guidance for the conduct of all research that involves human participants. Its purpose is to promote ethically sound human research; to set national standards of ethical conduct for all research involving humans; and to guide institutions, researchers and Human Research Ethics Committees (HRECS) in the ethical review and conduct of such research.

The TGA regulates:

- pre-market evaluation
- access to unapproved medicine
- licensing of manufacturers
- post-marketing monitoring
- export medicines

The TGA does not regulate reimbursement of the cost associated with treatments or the role of ethics committees in clinical trials.

Gene technology regulation

The Commonwealth Gene Technology Act, 2000 took effect on 21 June 2001. Its aims to protect the health and safety of people and the environment by identifying and managing risks posed by, or resulting from, GMOs that result from gene technology. The inter-governmental Gene Technology Ministerial Council received the report of the independent review panel on the statutory review of the *Gene Technology Act 2000* and the *Gene Technology Agreement 2001*, in Melbourne on 27 April 2006.

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Australia's National Approach to Clinical Trials

The Australian Government is working to enhance the clinical trials industry to maintain Australia's global competitiveness. The pharmaceutical industry and Australian, State and Territory governments have joined forces in a Forum on a National Approach to Clinical Trials. The Forum has identified initiatives to further improve the quality, timeliness, value and capacity of clinical trials in Australia. As a result, the NHMRC is taking the lead to coordinate a nationally harmonised system of scientific and ethics review of multi-centre research in Australia.

QCTN supports this initiative which will benefit all clinical researchers, service providers and sponsors in Australia.

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