



Review of the National Innovation System, 2008

-- Submission by the Queensland Clinical Trials Network Inc. (QCTN) --

What are the Goals of QCTN?

QCTN was established as an independent industry organisation representing those entities that provide clinical, pre-clinical trials and related services to both domestic and international sponsors.

QCTN brings together, and achieves global visibility for Australian providers from the private sector as well as the public sector, small as well as larger entities, and in general, any person or entity that is a "service provider" to customers from the worldwide industry sectors that include:

- innovative and generic medicines*
- the biotechnology sector*
- complimentary medicines*
- medical devices*

(*hereafter collectively described as 'bio-pharmaceutical and medical devices')

QCTN's priorities include a commitment to working with Governments, both State and Federal:

- to increase the recognition of the capabilities of the Australian services sector
- to ensure that appropriate metrics are used to measure the contribution of the services sector
- to increase investment in research and development:
 - by retaining a higher proportion of the Australian industry requirements for clinical and pre-clinical outsourcing
 - by attracting more international sponsors to undertake their clinical and pre-clinical requirements in Australia
- to create and maintain an attractive environment for undertaking clinical trials;
- to establish flexible regulatory, reimbursement, and tax regimes, which are globally competitive (thereby providing advantage to those sponsors who choose to undertake more of their research and development)
- to promote this knowledge based industry sector, and its contributions to the general public

Growth in the services industry is inextricably linked to constant innovation – indeed it is the services' providers that undertake the testing and have developed the expertise that support, test and validate the endless line of new and improved products and ideas from the bio-pharmaceutical and medical devices customers.



Because of global competition, and in order to support their customers, the service providers themselves must also continuously review their processes to ensure that their services offerings are providing innovative, reliable, state of the art, efficient and cost effective solutions.

This constant competition involves innovation, as successful growth in this industry depends on being able to meet the ever-increasing customer (and regulator) expectations.

The Productivity Commission's, Trade and Assistance Review 2006-2007, confirms that "there are significant market failures surrounding research and development and that a number of existing R&D assistance measures, while amenable to improvement, are likely to yield net benefits for the Australian community as a whole."

To create an effective and long-term environment of innovation and creative vitality, QCTN believes that Government support for the clinical and pre-clinical trials services providers will provide the capabilities and infrastructure required by the biopharmaceuticals and medical devices industry. This is after all an industry in which research and development sit at the very core of a viable business model, and should be guided by the following principles:

- A focus on maintaining and increasing net investment in research and development undertaken in Australia, through a well-designed (thus, cost-effective) investment attraction program.
- Support for partnerships and alliances across the value chain, and between global and local stakeholders, especially to facilitate the growth of small firms [such as biotechnology startups] conducting outcome-oriented research and development.
- A focus on developing incentives and an internationally competitive environment, with respect to globally competitive tax incentives (for both the service provider and the customer) to maintain and increase research activities and investment. The support of this sector will extend the domestic capabilities, and encourage investment so that Australian derived innovation will be able to be developed further - in a cost effective, locally-based services industry.

What does QCTN need from the Government?

Innovative industries such as the biopharmaceuticals and medical devices industry - and their services providers rely:

- on a highly skilled labour force,
- on strong intellectual property laws,
- on equitable access to domestic and foreign markets,
- on a transparent and efficient regulatory environment,
- on the government having the relevant metrics required to measure the services sector's contribution and impact
- on favorable Government policies, such as a globally competitive tax regime and strategic assistance that help to maintain and enhance a nation's competitive advantages.

In these areas, Australia can rightfully point to many achievements, however will Australia continue to be an attractive place for innovative industries to invest in?



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With the increasing competition and the changing dynamics of global trade, Australia will face increased challenges as an investment destination in the future, the Government must ensure that this country can continue to attract, and retain foreign and domestic investment in innovative and knowledge-intensive industries.

When compared to emerging economies such as Brazil, Russia, India, and China, Australia does not offer a cost advantage.

However we should encourage and implement policies and relevant metrics that specifically target our sustainable competitive advantages in conducting high quality research and development -particularly in the area of clinical trials. Access to a highly-skilled workforce and world-class universities, as well as public and private research institutions and service providers and global regulatory recognition and promotion of these capabilities, is the first step that needs to be taken.

Effective Taxation Regime - essential.

Reform of the R&D Tax Concession program will be important to this process. If tax incentives and changes to Australia's broader corporate tax regime are to be one of the cornerstones of Australia's innovation policy (and a key deliverable from the 2020 Summit), then they must be competitive with those countries that are our direct competitors.

Together with other stakeholders in Australian industry, QCTN welcomed the introduction of the 175% R&D Tax Concession (International Premium) in 2007 because it partially addressed the market failure relating to overseas ownership of intellectual property.

However, Australia's tax provisions remain uncompetitive; and they will not affect a change in corporate behavior in the global market place.

For taxation policy to be effective, the Australian Government is advised to identify those countries which Australia is likely to compete with between now and 2020.

In the biopharmaceuticals and medical devices industry, and their related services providers, our direct competitors currently appear to be, China, India, Ireland, Singapore, South Korea, Philippines, and increasingly the United Arab Emirates, Russia and Brazil. The average effective corporation tax rate in these countries is 15%; in Australia, the effective tax rate, taking into account existing concessions when applicable, is between 28% and 30%.

Tax incentives must apply to a broad range of activities, and research and development activities, which forms only one part of a much bigger value chain – is an area of competitive advantage we must build upon – in order to push activity along the value chain.

The resulting net increase in domestic income from utilization of tax incentives can then be returned to Government through personal income tax (additional employment), sales tax (additional sales), and property tax (additional facilities).

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Tax incentives and the corporate tax treatments alone are not the solution, thus strategic industry support becomes vital to maintain investment.

Past programs to support the Australian biopharmaceuticals and medical devices industry and consequently the services providers have worked well, both for the industry as well as for Australia. The rapid growth of the services industry over the last twenty years can be attributed to Government initiatives and ultimately an important contributor to Australia's prosperity – and for the reputation and quality results being achieved by Australian service providers

This support should continue because it constitutes a long-term collaboration between the Government and the industry in investing in the future socio-economic health of this nation.

What Further Areas Require Government Attention and Intervention?

According to the Pharmaceuticals Industry Action Agenda of 2002, there is room for improvement in Australia's commercialization culture. QCTN believes that this is still a major challenge for the Australian biopharmaceuticals and medical devices industry, and especially for the biotechnology sector – many sector entities believe they need to undertake their research and development activities offshore.

This is a concern, because we (Government, QCTN and other stakeholders) all need to continue demonstrating the numerous examples of where success has been achieved utilizing Australian services.

Significant gains from basic research and proof-of-concept activities are frequently lost because startups and small firms have inadequate access to advice (about Australia's capabilities) and funding, both locally and internationally, from multinational companies and the Government.

The Commercial Ready and Commercial Ready Plus programs have provided valuable support in this regard, but grants have so far been too small to facilitate large-scale commercialization projects.

In a recent report by the Government-endorsed Pharmaceuticals Education Council (PEC), it was identified that there is a considerable shortage of specific skills required not just by the biopharmaceuticals and medical devices industry and their service providers but all innovative, science-based industries in Australia.

QCTN has recognized this issue – and to the extent possible over the past 2 years has provided subsidized training programs (such as GCP Training) to its members so that they are able to provide services to a standard that will be recognized – and accepted by international regulators such as the FDA.

The PEC report identified gaps across the value chain, and especially noted that many recent university science graduates lack basic research, project management, clinical trial design, interpersonal, and marketing and negotiating skills, which are critical to research, development, and commercialization of innovative products. – this training is critically important for the services sector (and ultimately their customers – and years down the track the general public), and government support of such training will address a current hurdle being faced by the sector.



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Drug Discovery Research is characterized by an explosive development in the application of high-end computing, computational biology and molecular sciences. The convergence of these disciplines allows for a fundamental paradigm change in the way medical sciences and drug research are conducted. Examples in this context is the emergence of disease-centered visualization of biological pathways, the semantic web integrating information from disparate databases containing medically relevant information from around the globe and the availability of “the grid” instead of internet.

A comprehensive investment strategy for these converging disciplines accessible to the industry is advocated.

It is recognized that there is a need for facilitating a business approach to clinical trials management by Australian clinical trials service providers, in particular clinical trial sites in hospitals, in order to allow expansion of the clinical trials industry and positioning Australia as a destination for drug development.

Modern business practices associated with standardized information solutions for clinical trials need to be introduced in order to allow Australia’s clinical trial industry to reduce its business risks by meeting regulatory requirements and by being able to exercise the appropriate level of governance.

This is a key area of focus for QCTN, and we would invite timely Federal Government involvement with this initiative to allow an efficient time and cost effective implementation to those entities across Australia that are involved in provide clinical trial services - we would suggest that a ‘carrot and stick’ approach be used to encourage uptake of such an initiative and look forward to being able to provide a detailed suggested approach.

Biopharmaceutical and medical device companies should be encouraged to invest in Australian R&D by providing a rewards-scheme. This could be as simple as assisting with access to patients in publicly funded hospitals – from the early clinical trials to the ultimate marketed product

The basic concept of this scheme is that biopharmaceutical and medical device companies would be allowed to ask a PBS-accepted premium price for a new therapy provided that a particular threshold value of R&D has taken place in Australia. The details of the scheme require further investigation and we would welcome a discussion on how this may be delivered in a practical way.

During the 1990s, two Federal assistance programs, the Factor F scheme and the Pharmaceuticals Industry Investment Program, provided a powerful impetus for growth, and helped the industry invest billions of dollars and to create a services sector that has become a significant contributor to the socio-economic health of Australia.

However according to a recent survey, average investment levels have been declining since 2000. This may reflect the end of an investment cycle in Australia, following higher investment levels in 1990s, which demonstrates that over the next few years, if there isn’t a fresh approach, and if major investment is not encouraged and facilitated, the industry will face an environment of net divestment, as foreign direct investment is diverted to competitor nations.

The Australian biopharmaceuticals and medical devices industry still lacks critical mass necessary for long-term self-sustainability, and we need to continue to attract international pre-clinical and clinical trials – to continue to grow our capacity and experience.

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If we let this key part of the Value Chain flounder or disappear - then the maximal returns on investment (and their flow on effects) made by the biopharmaceutical and medical devices industry can not be achieved, and this means that as before - Australian innovation is not captured - but allowed to drift offshore. We must establish a culture of retention (for longer than is currently possible) and development of IP within Australia.

A lack of critical mass has made the Australian biopharmaceuticals and medical devices industry extremely vulnerable to the changing dynamics of global trade, especially within the context of the meteoric rise of emerging economies such as India and China. We must have the relevant preclinical and clinical infrastructure available here to allow this industry sector to grow and develop.

The Government can assist the Australian biopharmaceutical and medical devices industry and the related services providers, achieve critical mass through programs and incentives that encourage companies to

- Invest in additional R&D activity. At present, for example, less than 5% of the global industry's annual R&D budget is allocated to Australia for pre-clinical research and clinical trials,;
- Increase capital flows to earlier stages of the value chain (for Australian entities) to assist them with undertaking more of their preclinical and clinical trials with Australian service providers and thereby facilitate long-term self-sustainability for the industry.

Research matters because it has the power to improve people's lives.

The pay-off isn't always obvious and it doesn't always come immediately, but research advances our understanding and every pre-clinical and clinical trial teaches us something - even the ones that fail.

Knowledge-intensive industries are key drivers of economic growth. They improve productivity, support the growth of real wages and high-value exports, and enhance competitive advantage. The biopharmaceuticals and medical devices and related services industry is an excellent example of a knowledge-intensive industry.

This Australian industry has consistently shown very strong economic performance.

- Employment, has grown from approximately 10,000 in 1988 to over 34,000 in 2007.
- Annual R&D allocation grew from \$70 million in 1988 to \$752 million in 2007, or 7.5% (largest by a single industry sector) of Australia's business expenditure on research and development;
- And it contributed to significantly improving health outcomes for Australian citizens.

A number of QCTN's members will make individual submissions to the Review of the National Innovation System and we hope the proposals will inform the Review Panel's deliberations on how best to achieve innovative results for the Australian industry, as well as for the Australian community.

We look forward to a productive engagement with the Review Panel - and in turn Australian Government, and the Department of Innovation, Industry, Science, and Research.