Submission for McKeon Review – 23 March 2012

Why is it in Australia's interest to have a viable, internationally competitive health and medical research sector?

How can we optimise translation of health and medical research into better health and wellbeing?

- This submission is directed at the above questions with a focus on the translation of scientific research into new treatment options (drugs). The quality of basic scientific research in Australia is not matched by the quality or capacity to translate those ideas rapidly and consistently into treatments.
- This deficit reflects the fragmentation of investment and resources resulting in the absence of an industrial scale capability to move from targets to drugs.
- This important part of value creation is lost to the Australian economy, there is a failure to attract, develop and retain a skilled workforce in the field of drug discovery and there are inevitable delays in the time for major Australian scientific advances to be available to Australians and patients around the world.
- Project and program grants along with fellowship programs do not adequately support career paths for the talented and indispensable group of scientists who work to translate science into new treatments.

Cancer Therapeutics CRC (CTx) was established under the Commonwealth Government's Cooperative Research Centres program with a core understanding that the required capabilities existed within Australia to do industrial scale drug discovery but that focus and coordination was needed to produce an efficient and effective process. Drug discovery, especially when driven by novel biology, has a high risk of failure needing multiple projects and a significant level of investment to become established.

CTx has built an efficient drug discovery engine over the four years since its inception in 2007. This drug discovery engine has its key components in the universities, research institutes and CSIRO that are the participants in CTx. While the focus to date has been on cancer, the engine is largely agnostic for therapeutic area as long as the required translational biology expertise and resource is available. Some of the capabilities required to create the CTx engine were largely in place but others, such as a pharmaceutical industry styled medicinal chemistry capability, have required significant effort in directed international recruitment of the right people in order to build this capability to a critical mass. Having reached outside of Australia to find the right talent in this area we need to retain these key people and use them to build and train locally.

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The CTx model has within it systems to manage intellectual property and to direct value streams back to original research, to the capability providers and to shareholders in the organisation. This established collaborative model allows seamless project management and sharing of data via electronic notebooks amongst multiple nodes in different States. In contrast to many life science research projects that often direct investment to physical assets such as buildings and equipment the investment required to maintain and build on the CTx model is predominately in operating costs. In the medium term, once sufficient projects have been completed, the return in value will allow such an organisation to become self-sustainable.

The established model in Australia, in the field of biotherapy discovery and development, is CSL Limited. After a long history (1917 – 1991) as a Government funded and supported organisation it became an independent company in 1991 and publicly listed in 1994 and is now, only 18 years later, one of the top ten biotechnology companies worldwide.

Given the high cost of production and inherent limitations in delivery of these protein based biotherapeutics, there will always be a need for small molecule, “traditional” drugs. There is no significant commercial small molecule drug development in Australia.

Cyclical funding mechanisms, even with the degree of stability offered by the CRC Program, are in large part unsuitable to allow drug discovery capability to be established with sufficient bandwidth to complete enough projects to guarantee scientific and commercial success. To build on the current CTx model and expand it to encompass a broader range of therapeutic areas would require stable investment for an additional 9-11 years and involve a wider range of Australian institutions, especially in the translational biology field. In addition the market places a significant step up in value for drugs that have reached Phase 2 (proof of concept). The ability to bridge the gap, feed the existing Australian early stage clinical trial capability and take new drugs to proof of concept would increase international competitiveness and return on investment.

There is a significant shift in strategic thinking required to enable directed investments into operating costs over longer time periods rather than into capital projects. Such investments need not be open ended but can be tied to milestones as long as these are realistic. Investments of this nature will help attract, develop and retain a skilled research workforce while adding significant value to Australian science. The overall return on Commonwealth investments in health and medical research will be multiplied through successful commercialisation of science that has been translated into drugs within Australia rather than to default that translational process to organisations outside of Australia.