McKeon Review – submission from Cancer Trials Australia.

Cancer Trials Australia (CTA) is a network organisation of 14 clinical sites[1] and two research institutes[2], primarily in Victoria but expanding into NSW with two new sites this calendar year. The network coordinates multisite studies between its members and also provides project management services for the sites to commence trials. These services include preparation and submission of ethics and research governance packages (including negotiation of budgets/contracts) as well as ongoing ethics submission applications and management of finances for the life of the clinical trial. http://www.cancertrialsaustralia.com/Home.aspx

This submission is written for the cancer therapeutics sector of research based on our experience of managing cancer trials for over 10 years working with industry, government and both public and private hospitals. CTA currently manages over 200 trials in active stages of recruiting or in follow up.

CTA is making this submission as there has been a common theme associated with members wishing to join CTA. We have experienced exponential growth in CTA membership over the last four years from four clinical sites to 14. This has primarily been due to the need for sites to gain access to more novel agents for their patient population and to use the clinical trial as a robust patient treatment methodology. We have concerns that such access might be put as risk.

We are of the opinion that the CTA membership organisations have a higher proportion of newly diagnosed patients on clinical trials than national averages. As per other commentary in this area our members believe that more predictable clinical outcomes are likely if patients are on trial for the treatment of their cancer.

Our submission addresses each of the four questions raised by the panel

Why is it in Australia's interest to have a viable, internationally competitive health and medical research sector?
(Terms of Reference 1 and 6)

Australia's intellectual property in drug research is relatively small compared to the US and Europe. Australia will therefore grow more dependent on access to overseas drug research to contribute to improved health outcomes for our patients. CTA's focus is to have a globally competitive clinical trial network model and relies on a competitive health sector to provide this framework so that we can investigate, in a cost efficient and timely manner, any new chemical entities that may be sourced from overseas (as well as from Australian research institutes and

1 Alfred Health, Austin Health, Ballarat Health, Bendigo Health, Border Medical Oncology, Cabrini Health, Melbourne Health, Peninsula Oncology Centre , Peter MacCallum Cancer Centre , St Vincent's Health (Melbourne), Southern Health, The Royal Women's Hospital, Tweed Hospital, Western Health

2 Ludwig Institute for Cancer Research, The Walter and Eliza Hall Institute

biotech companies[3]). Competition for attracting that evaluation is intense and Australia's cost and efficiencies is no longer an attracting feature when compared to other Asia Pacific countries such as China, Korea and India as well as the emerging Eastern European market. The need for a health sector (public and private) that sees medical research as an investment rather than a cost and an ethics and governance process that is driven by overseas benchmarks, is absolutely essential to retain CTA's and Australia's current level of involvement in global research. This is also essential in minimising loss of skills from Australia due to a declining level of participation in global drug evaluation programs.

How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)

CTA's comments are directed at medical research funding.

It is our opinion that the current predominant basis of funding research based on researchers' record of peer review research publications needs to be complemented with;

a) Key performance indicators centred on metrics surrounding clinical trial activity and performance,

b) Secondary criteria such as appointments to scientific advisory committees of key global clinical trials groups, both in the private and public funded organisations.

c) Clinical Trial units within the institutions funded for trial performance and trial participation.

d) "Future Fund" established and contributed to by both Industry and the government. A percentage of revenue generated in Australia by pharmaceutical companies could form the basis of such a fund and grow with co-contribution from government. Alternatively, a contribution could be calculated based on clinical trial procedures broken down to standard care compared to trial paid procedures. Funds raised would predominately be used to increase the infrastructure of the clinical trial centre.

e) Increased focus and funding to Area Health Networks for attracting clinical trials and external funding from the private sector

f) Increase accessibility for protocol and statistical design and data management for investigator initiated trials nationally. Currently there are insufficient and only highly priced resources available to assist investigators to develop trials that can attract support. The data is inadequately compiled for independent evaluation by groups that would be in a position to fund further development.

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3 CTA provides Australian biotech. companies free initial advisory services on preclinical assessment and protocol design

What are the health and medical research strategic directions and priorities and how might we meet them? *(Terms of Reference 5, 12 and 13)*

CTA lists four areas which it believes are key priorities in medical research;

1. Clinical evaluation of biomarkers for improving targeted therapies
2. Integration of clinical trial activity and results into the eHealth records and sharing and use of information
3. Public funding of clinical trials units' infrastructure
4. Centralised tissue collection and storage and providing accessibly for investigator initiated trials.

How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)

1. Greater use of Clinical trial protocols into standard care: Integration of clinical trial databases into institution eScript products to alert clinicians to the existence of trials for their diagnoses.

2. Clinical trials metrics as part of CEOs KPIs in hospitals: Raise the importance of trials to a corporate financial level thereby triggering an analysis of return on such investments as described in strategic directions (see above).

3. More infrastructure funding to national collaborative clinical trials to increase participation and subsequent adoption of outcomes into standard care

4. Translation of pre-clinical/early phase (first time in human) studies into clinical trial programs: Greater infrastructure support for investigator initiated trials with a combination of more protected research time for clinicians and assistance preparation of protocols, statistical plans and clinical reports.