



Australian Government

CLINICALLY COMPETITIVE:
BOOSTING THE BUSINESS OF
CLINICAL TRIALS IN AUSTRALIA
CLINICAL TRIALS ACTION GROUP REPORT



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MINISTERS' FOREWORD

Australia is at the forefront of clinical research – an industry that trains and employs Australian professionals of the highest calibre – to provide world class medical treatment for life threatening and chronic illnesses. It is an industry that brings hundreds of millions of dollars annually into Australia's health system.

Australia's clinical trials industry has grown rapidly over the past decade. Some of our processes have not evolved to keep pace with this growth and, accordingly, need reform. This will ensure we maintain international competitiveness and secure investment so that all Australians can continue to enjoy the wide-ranging benefits to the health system that clinical trials provide.

We are very pleased to release the final report to Government of the Clinical Trials Action Group, *Clinically competitive: boosting the business of clinical trials*. The Australian Government endorses the report's recommendations.

The report addresses key issues including:

- the timeliness of clinical trial approvals,
- the benefits of e-health for clinical trials,
- improving patient recruitment, and
- the level of support for clinical trials networks.

The relevant Government departments and agencies will now work to implement all the report's recommendations within the timeframes outlined in the report. These are important microeconomic reforms that will lead to improved productivity and have benefits for patients, industry, researchers and governments. It is important that we put in place the right policies to ensure Australia remains a leading location internationally for clinical trials. The Commonwealth Government looks forward to working closely with the states and territories through the Australian Health Ministers' Advisory Council to ensure implementation of the report's recommendations.

The recommendations provided in this report are aligned with the Government's broader health reform agenda. This report touches on many areas that will also be improved by the implementation of the National Health Reform (NHR). In turn the NHR will provide an enhanced mechanism for delivering key recommendations of the report. Delivery of the reforms will ensure that patients receive high quality, better coordinated and sustainable health care over the coming decades.

We thank members of the Clinical Trials Action Group, the expert panels and those interested organisations and individuals who made submissions to the review, for their thoughtful consideration of the issues and their contribution to this important report.



The Hon Nicola Roxon MP
Minister for Health and Ageing



Senator The Hon Kim Carr
Minister for Innovation, Industry,
Science and Research

RECOMMENDATIONS

TO IMPROVE THE TIMELINESS OF ETHICS AND RESEARCH GOVERNANCE REVIEW

Recommendation A: That the Parliamentary Secretaries for Health and Innovation propose to the Australian Health Ministers' Advisory Council (AHMAC) that the states and territories:

- implement the National Health and Medical Research Council (NHMRC) Harmonisation of Multi-centre Ethical Review (HoMER) initiative by July 2011 through:
 - acceptance of a single ethical review for multi-centre human health and medical research; and
 - adoption of in-common policies, procedures and forms;
- adopt NHMRC's best practice research governance handbook for human health and medical research by July 2011 with a view to ensuring:
 - efficiency through national consistency of processes; and
 - adequate support structures for conducting clinical trials;
- introduce policy on clinical trials that:
 - provides an incentive to reach a thirty calendar day timeframe for both ethics and governance review for which sponsors would pay a defined additional amount to support increased efficiency;
 - supports a sixty calendar day maximum timeframe for governance review;
 - supports a sixty calendar day maximum timeframe for ethics review, the compliance with which would be a condition of certification of ethical review processes under the HoMER initiative;
 - allows concurrent review of the ethics and governance components of a clinical trial; and
 - allows a 'stop clock' during efficient ethics and research governance review when additional input is required before consideration can continue;
- monitor progress of these initiatives through jurisdictions publicly reporting annual data on the timeliness of ethics and governance review both for types and numbers of clinical trials in a consistent format; and
- include clinical trial activity and timeliness of approvals for clinical trials as a key performance indicator (KPI) when jurisdictions negotiate new agreements with public hospital Chief Executive Officers.

Recommendation B: That the Parliamentary Secretaries for Health and Innovation progress reforms, as outlined in Recommendation A, with the university and private hospital sector through Universities Australia and the Australian Private Hospitals Association.

TO PROVIDE FOR COST RECOVERY OF EFFICIENT CLINICAL TRIALS

Recommendation C: That the Parliamentary Secretaries for Health and Innovation propose to the AHMAC, that a table of standard costs associated with conducting clinical trials be developed for all trial sponsors in alignment with Australian Government health reform initiatives as they are introduced. This table should include:

- standard items developed by the NHMRC by July 2011;
- the efficient cost of the service reflecting the actual activity in accordance with cost recovery principles and determined by the proposed independent hospital pricing authority; and
- a reasonable additional payment to support the thirty calendar day timeframe for efficient ethics and research governance review outlined in Recommendation A.

TO ENSURE THAT CLINICAL TRIALS CAN TAKE ADVANTAGE OF THE DEVELOPING E-HEALTH SYSTEM

Recommendation D: That the Parliamentary Secretaries for Health and Innovation propose to AHMAC that it:

- introduce policy and/or systems that allow access (both on-site and remote) by clinical trial monitors and auditors to the electronic health records of clinical trial participants; and
- request National E-Health Transition Authority (NEHTA) and state and territory governments to make the clinical research system a key consideration when designing, developing and implementing e-health standards, specifications, strategies, frameworks, systems and programs. To that end NEHTA should:
 - explicitly examine its potential role in the development of specifications for interfaces between provider systems, trial registry and referral services; and
 - convene a forum of relevant stakeholders to examine existing ICT infrastructure supporting clinical trials and consider opportunities for improved functionality and interoperability to support trial approval, management and patient recruitment.

TO IMPROVE PATIENT RECRUITMENT

Recommendation E: That the NHMRC develop a consumer-friendly web portal that includes information on all current clinical trials in Australia. The portal would:

- provide access to Australian clinical trial information that is contained on searchable registries such as the Australian New Zealand Clinical Trials Register (ANZCTR), clinicaltrials.gov and the International Clinical Trials Registry Platform run by the World Health Organisation (WHO);
- link, with permission, to existing patient databases of consumer advocacy groups and existing clinical trials networks; and
- improve regular reporting on clinical trials activity in Australia.

Recommendation F: That the NHMRC and the Department of Innovation, Industry, Science and Research (DIISR) investigate by July 2011 the feasibility of creating a comprehensive and searchable web portal, similar to the US-based clinicaltrials.gov that would include (but not be limited to) the following functions:

- the capacity for potential participants and health practitioners to register their interest in future clinical trials, where those that have registered would be notified of new activity in their nominated therapeutic area(s);
- allow monitoring of trial outcomes;
- require all clinical trials conducted in Australia to be registered on it; and
- improve regular reporting on clinical trials activity in Australia.

Recommendation G: The forum of relevant stakeholders (identified under the second dot point of Recommendation D above) examine ways in which existing general practitioner software can be used to enhance patient recruitment.

Recommendation H: That DIISR work with DoHA, health consumer groups and other stakeholders to develop and distribute by July 2011, consumer information through GP and specialist offices, designed to encourage consumers to talk to their doctors about suitable clinical trial options,

TO FACILITATE BETTER NATIONAL COORDINATION AND GREATER COLLABORATION ACROSS CLINICAL TRIALS NETWORKS

Recommendation I: That greater support for clinical trials networks in priority health areas be provided through the NHMRC by:

- identifying the networks that exist in Australia by July 2011; and
- facilitating national coordination and encouraging collaboration across academia, clinical medicine and industry.

TO PROGRESS KEY CLINICAL TRIAL ISSUES

Recommendation J: That DIISR collate available material about the value and performance of Australian clinical trials.

Recommendation K: That the Pharmaceutical Industry Working Group (PIWG) becomes a mechanism for relevant stakeholders to continue to have input into clinical trials policy and co-ordinate implementation of improvements by:

- NHMRC regularly reporting the progress and success of the HoMER initiative; and
- periodically reviewing the progress of the above recommendations.

THE BENEFITS OF IMPLEMENTING THESE RECOMMENDATIONS ARE:

For Patients

- Continued rigour in the consideration of the scientific merit, the protection of participants and the safety of clinical trials;
- Improved access to information about clinical trials, their conduct and their outcomes;
- Maintained or improved access to clinical trials in Australia;
- Faster access to potential new treatments through clinical trials; and
- Faster access to evidence-based treatments based on knowledge gained in Australia.

For Industry

- Significant improvement in the timeliness, cost and consistency of clinical trials approvals;
- Standardisation and transparency of the costs for approval and conduct of clinical trials;
- Provision of benchmarked data on clinical trials performance that can be used to promote Australia's global competitiveness to global decision makers within the industry; and
- Increased patient recruitment into clinical trials.

For the Health system

- More efficient processes around ethical review and research governance for multi-centre clinical trials to optimise use of resources in the health system;
- Streamlining the use of clinical trials for ongoing process improvement in the health system;
- Ensured cost recovery within the health system for clinical trials participation; and
- Continued investment in Australia's medical research system which will, in many cases, reduce the public cost of treatment of trial participants.

For Researchers

- Faster start-up of trials providing more time to recruit patients into the trials; and
- Maintaining the current high level of global clinical trials activity in Australia to provide:
 - opportunities to gain experience and training for research staff via global clinical trials; and
 - opportunities to progress innovative Australian research ideas through increased opportunities for collaboration with industry.



THE HON RICHARD MARLES MP
PARLIAMENTARY SECRETARY FOR INNOVATION AND INDUSTRY

THE HON MARK BUTLER MP
PARLIAMENTARY SECRETARY FOR HEALTH

Senator the Hon Kim Carr

Minister for Innovation, Industry,
Science and Research

Parliament House
CANBERRA ACT 2600

The Hon Nicola Roxon MP

Minister for Health
and Ageing

Parliament House
CANBERRA ACT 2600

Dear Ministers

It is our great pleasure to present to you the Report of the Clinical Trials Action Group (CTAG).

The report is the culmination of six months of discussion, debate, consultation, research and deliberation by a team dedicated to the cause of strengthening and improving the Australian clinical trials environment.

We acknowledge the many people who contributed to our work through consultations and submissions – including governments, health professionals and other experts, health and consumer interest groups, and members of the general community. In particular, we would like to thank the members of the CTAG: Professor Jim Bishop AO, Australian Government Chief Medical Officer, Dr Tim Dyke, Executive Director, National Health and Medical Research Council (NHMRC), and Mr Mitch Kirkman of Novartis Pharmaceuticals Australia Pty Ltd and member of the former Pharmaceuticals Industry Strategy Group (PISG). We also acknowledge the contribution made by Professor Warwick Anderson AM, Chief Executive Officer of the NHMRC.

We would also like to thank the chairs of the five reference groups that provided much needed and valued input to this Report: Professor Richard Fox, Director of Research, St Vincent's Hospital, Melbourne; Professor John Funder, Senior Fellow, Prince Henry's Institute of Medical Research; Mr John Stubbs, Executive Officer, Cancer Voices Australia; Ms Carol Bennett, Executive Director, Consumers Health Forum of Australia Inc and Professor Jim Bishop.

A vibrant clinical trials environment in Australia ensures that Australian patients have access to the latest medical treatments while also representing an industry worth hundreds of millions of dollars.

Clinical research sits at the interface between academia, hospitals, patients and industry. This process has exposed a range of views as to the best approach to reforming the clinical trials environment in Australia for the benefit of all stakeholders. This report furthers the work of the earlier PISG which made recommendations for additional investigation of ways to improve timeliness of approvals, incorporating e-health initiatives and improving patient recruitment to clinical trials.

A number of factors have been identified in the recommendations that represent a first critical step in reforming the clinical trials environment to allow Australia to remain at the forefront of clinical research. Recommendations have been made that will address the timeliness of approvals through increased efficiency, gaining the benefits of e-health for clinical trials, improving patient recruitment and support for clinical trials networks. These recommendations are cognisant of the broader Australian Government health reform agenda.

We commend this report to you and hope it contributes to a sustainable, high quality, responsive clinical trials environment.

Yours sincerely



Richard Marles
Co-Chair
Clinical Trials Action Group



Mark Butler
Co-Chair
Clinical Trials Action Group

8 June 2010

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1. BACKGROUND TO THIS REPORT

CLINICAL TRIALS ACTION GROUP (CTAG)

The Minister for Health and Ageing, the Hon Nicola Roxon MP, and the Minister for Innovation, Industry, Science and Research, Senator the Hon Kim Carr, jointly announced the establishment of the Clinical Trials Action Group (CTAG) on 27 October 2009. The CTAG, which is a subgroup of the Pharmaceuticals Industry Working Group (PIWG), was tasked with boosting Australia's profile as a preferred destination for conducting clinical trials.

The CTAG initiative is in response to calls from the Pharmaceuticals Industry Strategy Group (PISG) to investigate priority reforms to the clinical trials operating environment to make Australia a more attractive location for such investment and activity.

MEMBERSHIP

The CTAG was co-chaired by the Parliamentary Secretary for Innovation and Industry, the Hon Richard Marles MP and the Parliamentary Secretary for Health, the Hon Mark Butler MP. The CTAG membership also included:

- Professor Jim Bishop AO, Australian Government Chief Medical Officer
- Dr Tim Dyke, Executive Director, Quality and Regulation Branch, National Health and Medical Research Council (NHMRC).
- Mr Mitch Kirkman, Manager, Process, Training and Quality, Novartis Pharmaceuticals and former member of the PISG.

Professor Warwick Anderson AM, CEO of the NHMRC has attended many meetings in an advisory capacity.

TERMS OF REFERENCE

The Terms of Reference were:

To work in consultation with relevant stakeholders, including state and territory governments, to improve the international competitiveness of the Australian clinical trials environment, including addressing the clinical trials recommendations of the PISG report through:

1. the development of a National Clinical Trials Roadmap, which prioritises and co-ordinates the many initiatives and stakeholders involved in clinical trial operations, to best leverage the varied public investments in clinical research, including a definition of roles and responsibilities for the recommendations of the Action Group;
2. investigation of the development of appropriate performance measures for clinical trials for inclusion in Australian Government funding agreements with states and territories;

3. investigation of how to ensure the rapid uptake of the NHMRC HoMER¹ multi-centre human research ethics approval process and adoption of best practice institutional processes for research governance approval. Strategies may include concurrent reviews of ethics and research governance;
4. development of strategies to increase patient recruitment for clinical trials; and
5. development of a Clinical Trials ICT Strategic Plan, with the purpose of systemically maximising efficiencies from the application of ICT in the assessment of trial feasibility, trial approval, trial establishment and conduct of clinical trials.

METHODOLOGY USED TO ADDRESS THE TERMS OF REFERENCE

The CTAG met on six occasions to address the terms of reference. Broad consultation was considered essential. To facilitate this, the CTAG established five expert Reference Groups with representation from industry, research institutions, hospitals, patient support groups, consumer groups, federal and state governments and academia. Membership of the Reference Groups is provided at Appendix 1.

Each Reference Group was directed to consider a single term of reference. To guide the Reference Groups, the CTAG developed five discussion papers, one for each term of reference.

To further encourage and facilitate broad consultation, an early action of the CTAG was to call for public submissions, and publish the five discussion papers on the Department of Innovation, Industry, Science and Research (DIISR) website www.innovation.gov.au/clinicaltrials.

The Secretariat, led by DIISR with strong support from the Department of Health and Ageing (DoHA), provided analytical support to the project.

To foster national cooperation, the co-chairs wrote to the states and territories in late November 2009 describing the establishment of the CTAG and urging them to encourage the uptake of the HoMER project in their respective jurisdictions.

Public interest was strong. Submissions were received from a broad range of stakeholders, from state government departments, medical and industry associations, consumer groups, private persons and pharmaceutical companies. The Secretariat received 54 public submissions of which four were provided in confidence. A list of the public submissions is provided at Appendix 2. Analysis of the submissions indicates that the majority acknowledge the discussion papers and raise issues that were also identified by the Reference Groups. Overall, the quality of submissions was high, reflecting the level of stakeholder interest in improving the environment for clinical trials in Australia.

STRUCTURE OF THE REPORT

The structure of the report follows the configuration of the recommendations rather than terms of reference. However each of the terms of reference has been considered and addressed within the report.

¹ Harmonisation of Multi-centre Ethical Review (HoMER) viewed 1 April 2010
http://www.nhmrc.gov.au/health_ethics/homer/index.htm

2. OVERVIEW OF THE AUSTRALIAN CLINICAL TRIALS SECTOR

BACKGROUND TO CLINICAL TRIALS

Clinical trials are one of the proven methods of clinical practice improvement and innovation. They represent a major research activity in Australia and a major investment nationally and internationally, with \$2.8 billion spent on health R&D in Australia in 2004-05, where clinical trials were a major component.²

The conduct of clinical trials in Australia involves not only the pharmaceutical and biotechnology industries, but also many different research institutions and hospitals, and governments and other organisations concerned with healthcare, research, education, training and commercialisation. Collaboration among these elements is an important factor influencing the success of clinical research for our population and economy.

Major clinical practice improvements leading to substantial gains in health outcomes for our population have resulted from clinical trials. These trials include screening, early treatment and new important therapeutics or improved clinical management and medical procedures.

Australia has a proud history of conducting innovative and high quality clinical research. Significant growth has occurred over the last 20 years, in the number of clinical trials supported by academic institutions and the pharmaceutical industry across all phases of clinical development. In a global context, Australia has traditionally been perceived as a relatively attractive place to undertake high quality clinical trials, being able to deliver these within reasonable timeframes and at a reasonable cost.³ Australia has contributed intellectually to the design and conduct of trials through academic leadership.

A vibrant clinical trials research sector:

- provides the evidence for rapidly and directly improving health outcomes;
- attracts and retains high quality clinicians in Australia and improves the skills and knowledge of clinical staff by implementing the latest clinical improvements;
- improves clinical standards while promoting academic evidence-based practice; and
- attracts substantial national and overseas research dollars to Australia that provides significant funding of research infrastructure.

Generally patients on trials have better outcomes due to close monitoring and careful application of the best evidence-based clinical care. New, improved treatments are often available many years in advance of commercial availability at lower cost to the health sector and providing immediate benefit to patients on trials. Other patients subsequently benefit faster from the lessons learnt from well documented clinical trials.

² Access Economics. June 2008, Exceptional Returns: the value of investing in health R&D in Australia II. Australian Society for Medical Research

³ Economist Intelligence Unit, 2005, Benchmarking Study of the Characteristics of the Australian and International Pharmaceuticals Industries, Department of Industry, Tourism and Resources, Canberra; viewed 1 April 2010: http://www.innovation.gov.au/General/Innov-PS/Documents/Pharma_Benchmarking_Final_Sept20051007095438.pdf

An active clinical trials research sector also brings benefits to the Australian economy; around \$100 million is saved each year in the health care costs of people on trials where standard treatments are subsidised by clinical research funding. It encourages innovation through collaboration between healthcare, education and research sectors and industry both within and outside Australia.

Thus there are strong motivating factors to identify effective methods to improve participation in trials and to increase industry investment in clinical trials.

Australia is competing internationally for investment in clinical trials. Measures to increase the attractiveness of conducting clinical trials in Australia need to support both strong and independent clinical research capacity as well as increased pharmaceutical and biotechnology industry investment, as these sectors enhance and complement each other.

CURRENT ACTIVITY IN AUSTRALIA

The Therapeutic Goods Administration (TGA) provides basic information on all clinical trials conducted in Australia using unapproved therapeutic goods (drugs, biologicals and medical devices), or using approved goods for non-approved purposes, under their Clinical Trials Notification (CTN) and Clinical Trials Exemption (CTX) schemes⁴. The number of notifications, an indication of new trial activity in Australia, peaked in 2006-07 and declined the following year and has not reached the peak of two years previously (see Table 1).

Table 1: Clinical Trials Notifications: 2003 – 2009⁵

Financial Year	Total Number of Notifications
2003 – 04	2378
2004 – 05	2776
2005 – 06	2576
2006 – 07	3182
2007 – 08	2792
2008 – 09	2986

In early 2010, the pharmaceuticals industry conducted a benchmarking survey of industry-sponsored clinical research in Australia.⁶ It collected data based on 2009 activity where 18 of 54 companies responded. Note that investigators who did not participate in industry trials did not have the opportunity to respond to the survey. Some headline information revealed by the survey is as follows:

- A total of 1265 clinical trials were being conducted by the respondent companies in 2009;
- The total number of patients enrolled in these trials was 18,600;
- Of these 1265 clinical trials, 366 were commenced in 2009;
- 899 trials were ongoing from prior to 2009;
- Most of the new trials were Phase III (118);

⁴ Clinical trials at a glance, viewed 9 April 2010, <http://www.tga.gov.au/ct/ctglance.htm>.

⁵ Internal Therapeutic Goods Administration Half-Yearly Performance Report (January - June 2009).

⁶ Medicines Australia & Pharmaceutical Industry Council Research and Development Task Force, 2010, *Clinical Trials in Australia - A Report on the Characteristics of the Clinical Trials Industry in Australia*

- The smallest category of new trials was Phase IV (28);
- The respondent companies spent a combined total of over \$214 million on clinical trials in 2009; and
- In cases where trials were cancelled or sites were closed prior to commencement of patient recruitment, 63 per cent were due to governance delays and 37 per cent were due to Human Research Ethics Committee (HREC) delays.

VALUE AND IMPORTANCE OF CLINICAL TRIALS

The clinical trials sector is worth around \$1 billion per annum to Australia with direct foreign investment of over \$450 million per annum. The pharmaceuticals industry has estimated that pharmaceuticals clinical trials alone are worth \$450 million each year in Australia.

Australia attracts a significant and growing number of Phase I clinical trials. This is due to a number of factors including, fast approval processes, high quality clinical practice and academic clinical trials centres. Although a much smaller sector than the Phase II-IV trials sector, it does have further growth potential. The value of “first-in-human” studies is to provide the capacity to translate discoveries from Australia’s first class biomedical research sector into clinical practice.

Phase II – IV clinical trials are those most likely to change clinical practice for the better. Later stage clinical trials (i.e. Phase III clinical trials) are less dependent on close collaboration between clinicians and pre-clinical researchers. They are more expensive to conduct and therefore industry is more sensitive to these costs. This is also true for bioequivalence studies for generic drugs, which are becoming increasingly cost sensitive.

Companies may be more likely to conduct later stage clinical trials in Australia if early stage trials have already been conducted here. However companies may prefer to conduct later stage clinical trials in the key markets for potential commercial return. This has provided difficulties for Australia given our relatively small market size.

The quality of both our academic clinical leaders and healthcare infrastructure, and an ethnically diverse, informed population makes Australia a good location for all stages of clinical trials. However, there is anecdotal evidence that the approval process for later stage multi-centred clinical trials, as opposed to first-in-human studies, is slower in Australia than in some other comparable countries. In particular, the discordant increase in the time taken and cost of obtaining separate ethics and governance approvals for each site of a multi-site trial (typically Phase II and III clinical trials) disproportionately increases the cost and time burden for these trials. Any clinical practice improvements resulting from these trials are therefore also delayed. Delays in gaining approval and in recruiting patients are contributing to a decline in Australia’s competitiveness.

These are not the only barriers impacting on Australia’s ability to attract later stage clinical trials. Australia is facing increasing competition from developing countries that are improving their capacity to perform later stage clinical trials for lower costs. The larger patient populations of these countries also provide companies with larger potential commercial markets.

Global rationalisation trends of industry and emerging competition from lower-cost centres may threaten Australia’s long term competitiveness as a destination for clinical trials run by the global pharmaceutical industry. Australia’s competitive advantage lies in being a highly skilled, cost-effective and timely place to conduct high-value drug development activities, not in being the lowest cost location.

INTERNATIONAL INITIATIVES TO IMPROVE THE OPERATIONS OF CLINICAL TRIALS

There are numerous initiatives from around the world aimed at improving the performance and attractiveness for investment in clinical trials. Significant examples include the UK National Institute of Health Research Clinical Research Network; the US National Institutes of Health clinical trials networks; and KoNECT, a Korean Government initiative.

Elements of these initiatives could improve the clinical trials environment in Australia but careful consideration is needed to determine whether they are appropriate and able to be implemented in the Australian context.

EXISTING INITIATIVES OF AUSTRALIAN GOVERNMENTS TO FACILITATE CLINICAL TRIALS

Governments at Commonwealth, state and territory levels in Australia are involved in a range of initiatives aimed at improving the performance and attractiveness for investment in clinical trials in Australia, from regulating the activity (eg ethical and scientific review, privacy, e-health) to providing funding and infrastructure to universities, hospitals, research institutes and companies.

Examples of Australian Government initiatives to provide direct support for clinical trials and clinical research include: the TGA Clinical Trials Notification (CTN) Scheme; Cancer Australia; and NHMRC grants which include funding for the Australian New Zealand Clinical Trials Register (ANZCTR).

The NHMRC is a major government funder of health and medical research and has provided funding for clinical research via:

- Centres of Clinical Research Excellence;
- Clinical Practitioner Fellowships;
- Clinical Career Development Awards; and
- Enabling grants, program grants, project grants (including large scale clinical trials) and partnership projects in clinical areas.

In 2009, the NHMRC funded more than \$215 million in clinical research.

State and territory initiatives, include:

- Cancer Institute NSW, Clinical Trials NSW and the NSW system for single ethics review of multi-centre research;
- Victorian Cancer Agency, Nucleus Network, Cancer Trials Australia and streamlining multi-centre ethical review in Victoria;
- South Australia's Bio Innovation SA and Drug Development South Australia;
- Western Australian Government funding the establishment of a Phase I and Phase II research facility;
- Queensland Clinical Trials Network (QCTN), BioPharmaceuticals Australia (BPA) and single ethical review of multi-centre research for Queensland Health; and
- ACT's Health Research Office.

PROPOSED COMMONWEALTH INITIATIVES:

Two proposals that would potentially provide significant benefits if implemented are:

- **The R&D Tax Credit**

Under the proposed R&D Tax Credit (as per the second exposure draft), Phase I, II and III clinical trials will be eligible where they are core R&D or where they are conducted for the dominant purpose of supporting core R&D. Some support may also be available for eligible overseas R&D activities where they cannot be performed in Australia and have a significant scientific link to the R&D performed in Australia.

- **National Health Reform (NHR)**

On 13 February 2011 at the Council of Australian Governments (COAG), the Commonwealth and all States and Territories signed a Heads of Agreement on National Health Reform (NHR).

Under NHR, the Commonwealth and all states and territories will work in partnership to improve health outcomes for all Australians and secure the long-term sustainability of Australia's health system. The Commonwealth will increase its contribution to efficient growth funding for hospitals to 45 per cent from 1 July 2014, increasing to 50 per cent from 1 July 2017. A guaranteed additional \$16.4 billion will be provided by the Commonwealth for public hospitals services under this new agreement up until 2019-20. This funding is in addition to base funding already provided by the Commonwealth.

Under NHR the governance of the health and hospitals system will devolve to new local institutions – Local Hospital Networks (LHNs) and Medicare Locals. COAG have agreed to the establishment of a national approach to Activity Based Funding and that public hospital services will be funded, wherever possible, on the basis of a national efficient price for each public hospital service provided to public patients. An Independent Hospital Pricing Authority will be established to determine the efficient price of hospital services. A National Health Performance Authority will also be established to develop and produce reports on the performance of hospitals and health care services, including primary care services.

All governments will contribute funding for hospitals into a single national pool which will be administered by an independent national funding body. There will be complete transparency and visibility of government contributions into the pool and from the pool through state and territory accounts to LHNs. As well as amounts paid to LHNs, funds will flow from the pool to the states and territories for block funding for small regional and rural hospitals and to fund teaching, training and research undertaken in public hospitals.

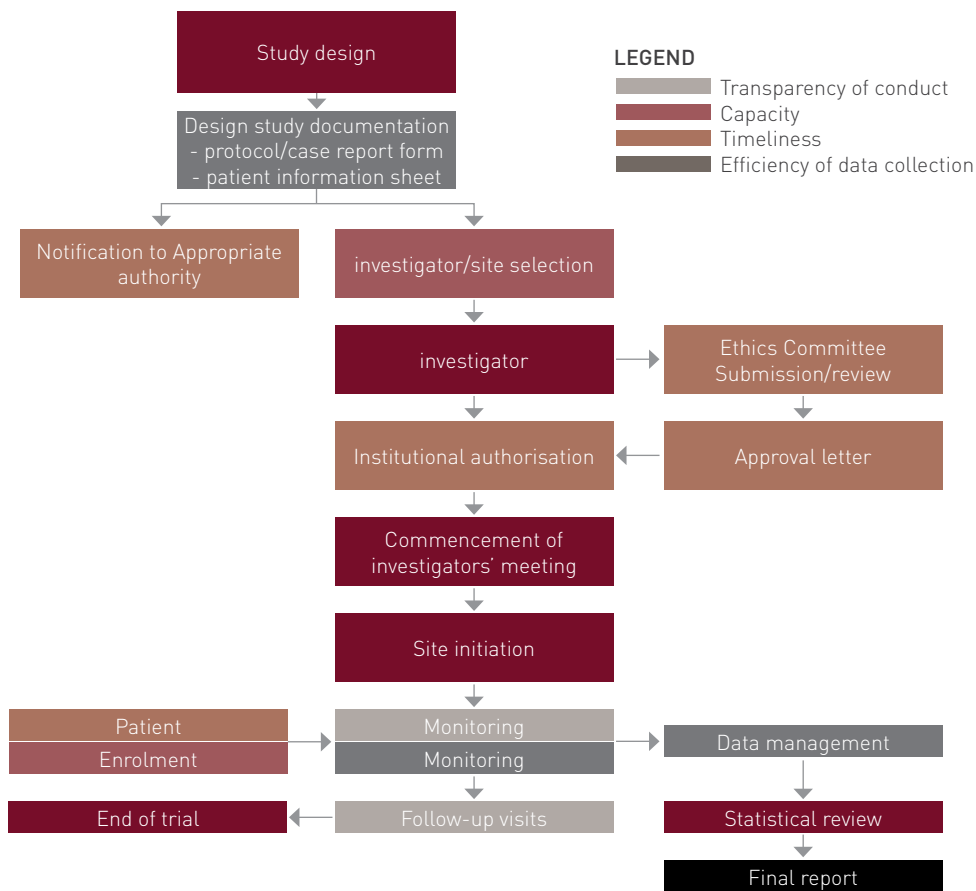
Additionally, the Australian Commission for Safety and Quality in Health Care will be established as a permanent, independent authority that will develop, monitor and implement national standards for improving clinical safety and quality in hospitals and health care settings.

3. IMPROVING CLINICAL TRIALS APPROVALS

Before a clinical trial in humans can begin, ethical and scientific review and approval for the trial must be completed. In addition, a separate review and approval of research governance matters must also be completed for each site at which the trial is to be conducted. The requirement for separation of ethical scientific review from research governance considerations is part of the 2007 National Statement on the Ethical Conduct of Research involving Humans (NS 2007).

The process of seeking ethics approval and conducting clinical trials is complex as shown in Figure 1.

Figure 1: Overview of clinical trials process⁷



Source: adapted from <http://www.qualityfirstint.com/services/ctp.htm>

CURRENT STATUS OF HUMAN RESEARCH ETHICAL REVIEW

At present the majority of HRECs that receive applications to review clinical trials are based in the institutions in which the study is to be conducted. In general, these HRECs are sub-optimally resourced, reflecting tight institutional budgets and the growth in clinical trial activity over the past decade.

⁷ The legend identifies the key criterion driving investment location decisions for global trials, with the chart identifying the relevant trial stage impacting on performance against these criteria.

Starting in 2007, NSW instituted a system of single ethical review (and acceptance by other institutions) within the NSW public health system. Since its introduction, the system has considered 1,093 multi-centre applications and saved about 2,000 duplicate reviews.⁸ Further development and implementation of processes to improve the quality (including timelines) of ethical review is evolving, nationally and internationally. Recently Victoria introduced procedures for single ethical review for multi-centre clinical trials. Tasmania has established a single ethics committee for the state, and Queensland will implement a single intra-state ethical review system in the latter half of 2010.

CURRENT STATUS OF RESEARCH GOVERNANCE REVIEW AND TRIAL AUTHORISATION

NS 2007 explicitly states that institutions must avoid unnecessary duplication of ethical review for multi-centre research. It also explicitly states that the ethics and scientific review responsibilities of an institutional HREC should be clearly separated from the institution's research governance processes. In terms of the latter, NS 2007 places the responsibility on institutions to ensure that appropriate personnel, structures and processes for research governance are in place.

Few institutions are yet to clearly separate the administrative support for HRECs from that required for research governance, and in some cases governance issues are still inappropriately dealt with by HRECs. In the context of single ethics review for multi-site trials, NSW, Victoria and Queensland have initiated site specific assessments (SSA) whereby institutions conduct a site review and authorise the study to commence. In NSW this has led to significant workloads for researchers (SSA submissions) and governance officers (review), on occasion lengthening rather than streamlining the authorisation process⁹.

CURRENT STATUS OF THE NATIONAL SINGLE ETHICAL REVIEW OF MULTI-CENTRE HUMAN RESEARCH (HOMER) INITIATIVE

In 2006 AHMAC supported the NHMRC developing a national system for the single ethical review of multi-centre human research. The objective of the HoMER initiative is to increase the efficiency of institutional ethical review processes underpinning Australian health and medical research, including clinical trials, by eliminating review duplication. In line with HoMER, the ethical review of a single HREC would be used by all research partner institutions in their participation in a given study. The NHMRC has been working with stakeholders including the jurisdictions and the pharmaceutical industry to develop key elements of a national approach.

The initiatives described above being undertaken in NSW, Victoria, Tasmania and Queensland should support both confidence in, and appreciation of, the institutional benefits of the single ethical review process, and in so doing support the uptake of the HoMER initiative Australia-wide.

The Pharmaceutical Industry Council and Medicines Australia have demonstrated their willingness to work with various stakeholders to develop better protocols for clinical trial management. Examples are the Clinical Trial Agreements developed in collaboration with the eastern mainland

⁸ Grow Your Knowledge Pty Ltd, August 2009, *Evaluation of the NSW Department of Health Model for Single Ethical Review of Multi-Centre Research*, viewed March 2010, http://www.health.nsw.gov.au/pubs/2009/model_ser.html (page 7).

⁹ Sian *et al*, A case study evaluation of ethics review systems for multicentre clinical trials. *The Medical Journal of Australia*, 2009; 191: 280–282.

states and the revised serious adverse event reporting requirements developed jointly with the NHMRC. This willingness to cooperate bodes well for successful joint tackling of areas of need identified in the HoMER roll-out process, and the clear support for harmonisation by the pharmaceutical industry.

The environment in which ethical review operates is complex. Progress has been made by the NHMRC over the past two years to develop standard forms and the tools needed for institutions to have their ethical review processes HoMER-certified. The national certification scheme is underway, with the first round to be finalised in mid-2010, with forty institutions currently progressing through the certification process. A register of institutions with certified ethical review processes will then be made publicly available, allowing research leaders and sponsors of clinical trials to select a HREC from this register to approach for single ethical review of a multi-centre research project.

ROADBLOCKS TO ADOPTION OF HOMER

While the idea of reducing workload through eliminating duplicated review might logically appear attractive, to date the practice has not been consistently adopted by institutions working across jurisdictions. There are several reasons why this may be so.

Structural issues hindering the uptake of HoMER include:

- the experience in a number of cases that ethical review is less of an issue, in terms of time elapsed, than governance implementation;
- the variety of IT systems in use in different jurisdictions and institutions;
- the differences between state and territory jurisdictions legal requirements for ethical approval; and
- the need for a central advisory and dispute resolution system.

Additional reasons why single ethical review has not been adopted across institutions include:

- research ethics offices are under-resourced and under-staffed leading to offices being unconvinced of their ability to take up single ethical review;
- a lack of understanding of single ethical review by institutional CEOs, and of the benefits of institutional engagement;
- concern over questions of insurance and indemnity in case of misadventure following ethical review elsewhere;
- a lack of recognition that uptake of HoMER is an evolving process, and waiting until the process is complete before joining in;
- concern that while the workload may fall, the time until approval may nevertheless not be shortened, based on the initial NSW experience; and
- concern with the detail and complexity of the processes required for the certification of reviewing HRECs under HoMER.

MEASURES NEEDED TO ENABLE INSTITUTIONS TO SUPPORT THE RAPID UPTAKE OF HOMER

It is important that the processes of uptake and implementation of HoMER should not make additional demands on the resources or processes currently in place within institutions for ethics and governance review. Even though, as noted above, HoMER should free up research office personnel to concentrate on governance issues, many institutions will retain HRECs for internal purposes. Certification of some HRECs may thus require additional institutional resources for adequate governance to be set in place.

In order to extend single ethical review from within-state to across-Australia, it will be necessary to ensure that institutional CEOs and hospital boards are assured that their indemnity status will continue. In addition, research governance officers must be confident that researchers comply with state and territory jurisdictional requirements. It is valuable to note that state and territory insurers have endorsed the proposal in which any institution that has their ethics approval process certified by HoMER will be indemnified against misadventure by the state or territory in which they operate. This will be the case regardless of the origin of the HREC approval or the location of the clinical trial within Australia.

Under HoMER, differing legislation between the jurisdictions of the HREC and the institution conducting the research needs to be taken into account during ethical and governance review (this is mainly a governance issue). For example, guardianship legislation affects how consent is sought for potential research participants unable to consent for themselves. In Western Australia, no studies other than observational on incapacitated persons are legal, whereas in Queensland, NSW and Victoria, a delegated authority may provide consent to participate in interventional research.

ROADBLOCKS TO TIMELY ETHICAL REVIEW AND MEASURES TO OPTIMISE REVIEW PROCESSES

The present institutional HRECs follow a general template laid down thirty years ago. In Australia there are estimated to be approximately 250 HRECs (approximately 230 registered with the NHMRC). The busiest meet eleven times per year, requiring applications to be lodged more than two weeks in advance, and with decisions conveyed to applicants commonly within seven to ten days of the monthly meeting. The composition of ethics committees is mandated, and members are almost universally unpaid. It is often very difficult to attract and retain appropriate personnel, whose time for activities beyond service/teaching/research is commonly constrained.

There is a widely held view that the time taken for ethics committees to review and approve applications can be unnecessarily excessive. There are many legitimate reasons for delays in ethical approval, including concerns about protection of participants of clinical trials. On many occasions, the stated reasons for delays are trivial or in fact governance issues. Separation of ethics review from governance, implicit in the HoMER initiative, should assist in enabling institutions to identify and address these issues.

ROADBLOCKS TO TIMELY RESEARCH GOVERNANCE IMPLEMENTATION

Whereas research ethics committees in many institutions have been functioning for many years in terms of constitution and processes, the area of research governance is much less broadly developed. The *Australian Code for the Responsible Conduct of Research (2007)*, the *NS2007* and their antecedents set out high level principles, but ambiguities remain in the roles and responsibilities of different parties.

Commonly, a single research office not only serves to administer the ethics committee(s) in the institution, but is also responsible on an institutional basis for the complexities of research governance. Such complexities include insurance, indemnity, contracts and legal issues, adverse events, monitoring, reporting, and acquittance. These issues require a range of staff and skills currently rarely present in such offices.

One corollary of this situation is that, on occasion, implementing governance arrangements takes longer than obtaining ethical approval. Another is that on many occasions governance issues are inappropriately referred to ethics committees. A third is that important aspects of governance (for example, random review as part of monitoring) are rarely possible.

It should be noted that responsibility for timely and efficient research governance rests not only with the designated officers, but also with the range of individuals involved in clinical trials – researchers, research coordinators, clinical research organisations, trial sponsors. All of these officers need to be able to provide prompt responses to the questions required for timely authorisation to be granted.

TIME TAKEN FOR CLINICAL TRIALS APPROVALS

The time taken to complete ethics and research governance review in Australia seems to be becoming increasingly lengthy^{10, 11}. It is also highly variable as shown in a 2009 industry survey where ethics review took 14 to 297 days and research governance 2 to 350 days¹².

Some state and territory governments have introduced time benchmarks for ethics and research governance review to encourage efficiency, for example: Queensland - sixty calendar days for ethics and twenty-five calendar days for research governance; Victoria - thirty working days for ethics; and New South Wales - sixty calendar days for ethics. To support these benchmarks, state governments have adopted a 'stop clock' for review, performance indicators and HREC accreditation. Queensland Health has incorporated their benchmarks as performance indicators for the District Health CEOs¹³. The ability of a reviewing HREC to meet review benchmarks is required for continued accreditation under the NSW system¹⁴. As these systems were only implemented relatively recently, their impact on timeliness will be more certain over the coming years.

¹⁰ Sian *et al.*, A case study evaluation of ethics review systems for multicentre clinical trials. *The Medical Journal of Australia*, 2009; 191: 280–282.

¹¹ Medicines Australia & Pharmaceutical Industry Council Research and Development Task Force, 2010, *Clinical Trials in Australia - A Report on the Characteristics of the Clinical Trials Industry in Australia*

¹² Medicines Australia & Pharmaceutical Industry Council Research and Development Task Force, 2010, *Clinical Trials in Australia - A Report on the Characteristics of the Clinical Trials Industry in Australia*

¹³ Queensland Government, 2008, Research Management Policy and Framework, viewed March 2010, http://www.health.qld.gov.au/ohmr/documents/res_man_pol_fram08.pdf.

¹⁴ NSW Department of Health, 2007, *Research - Model for Single Ethical & Scientific Review of Multi-Centre Research [PD2007_072]*, viewed March 2010 http://www.health.nsw.gov.au/archive/policies/pd/2007/PD2007_072.html.

To further encourage efficient review of ethics and research governance there may be a case for providing a reasonable additional payment to support timely and efficient review. Consideration needs to be given to what should be a reasonable payment and how it would be made. More efficient reviews would benefit the whole Australian clinical trials sector.

PERFORMANCE MEASURES FOR CLINICAL TRIALS

The Productivity Commission's recent report into public and private hospitals argued that '... hospitals vary significantly, and reporting broad statistics masks the major variation that can occur between hospitals, as observed by the Australian Commission on Safety and Quality in Health Care. It is hospital-level data, not jurisdictional, that health care consumers, providers, funders (private health insurers and governments), regulators and policy makers need to inform their decisions.'¹⁵

A recurring theme during stakeholder consultations in developing the National Health Reform (NHR) report was the need to collect relevant datasets in a nationally supported and consistent manner. To support clinical trials across Australia, the NHR could enable the collection of national datasets such as:

- patient data for epidemiological studies, and feasibility studies to determine whether there are enough potential patients to fill a particular trial at a specific hospital; and
- hospital performance data around clinical trials in areas such as: timeliness, cost of trials, participation rates, comparisons with overseas counterparts (if applicable), the phases of trials covered, the number of patients per trial, the number of employees involved in trials and their field of expertise, and the clinics engaged in clinical trials and their area of expertise.

The establishment of the NHR could introduce a wider set of national reporting that would include data relevant to clinical trials.

The establishment of the NHR could introduce hospital KPIs relating to clinical trials activity and timeliness, to ensure that clinical research is a priority in the healthcare system and is supported.

UNIVERSITIES AND PRIVATE HOSPITALS

Once KPIs have been established in the public system, these indicators will set the accepted performance benchmarks for Australia that will influence placement of trials in the university and private hospital sectors. A process of engagement with these groups, via Universities Australia, and the Australian Private Hospitals Association, to garner their participation in the single ethical review process and encourage rapid uptake of streamlined governance timelines, practices and systems implemented under HoMER, will be necessary.

¹⁵ The Productivity Commission, 2009, *Public and Private Hospitals* (p. 57)

IMPROVING THE TIMELINESS OF ETHICS AND RESEARCH GOVERNANCE REVIEW

As outlined above, a number of factors are currently impacting on the timeliness and efficiency of the approval processes for clinical trials in Australia. These include slow uptake of single ethical review, undeveloped and inconsistent processes for governance review and poor support structures for both ethics and governance approval processes. In order to significantly and consistently accelerate multi-centre clinical trial site start-up across Australia, the CTAG proposes the following to address these issues:

Recommendation A: That the Parliamentary Secretaries for Health and Innovation propose to the Australian Health Ministers' Advisory Council (AHMAC) that the states and territories:

- implement the National Health and Medical Research Council (NHMRC) Harmonisation of Multi-centre Ethical Review (HoMER) initiative by July 2011 through:
 - acceptance of a single ethical review for multi-centre human health and medical research; and
 - adoption of in-common policies, procedures and forms;
- adopt NHMRC's best practice research governance handbook for human health and medical research by July 2011 with a view to ensuring:
 - efficiency through national consistency of processes; and
 - adequate support structures for conducting clinical trials;
- introduce policy on clinical trials that:
 - provides an incentive to reach a thirty calendar day timeframe for both ethics and governance review for which sponsors would pay a defined additional amount to support increased efficiency;
 - supports a sixty calendar day maximum timeframe for governance review;
 - supports a sixty calendar day maximum timeframe for ethics review, the compliance with which would be a condition of certification of ethical review processes under the HoMER initiative;
 - allows concurrent review of the ethics and governance components of a clinical trial; and
 - allows a 'stop clock' during efficient ethics and research governance review when additional input is required before consideration can continue;
- monitor progress of these initiatives through jurisdictions publicly reporting annual data on the timeliness of ethics and governance review both for types and numbers of clinical trials in a consistent format; and
- include clinical trial activity and timeliness of approvals for clinical trials as a key performance indicator (KPI) when jurisdictions negotiate new agreements with public hospital Chief Executive Officers.

Recommendation B: That the Parliamentary Secretaries for Health and Innovation progress reforms, as outlined in Recommendation A, with the university and private hospital sector through Universities Australia and the Australian Private Hospitals Association.

COSTS FOR ETHICS AND RESEARCH GOVERNANCE REVIEW AND OTHER CLINICAL TRIALS ACTIVITIES

The fees charged for the review of an ethics and research governance application are typically two tiered. In Queensland, Victoria and NSW, industry sponsored trials are charged anywhere between \$3300 and \$8500 per application whereas non-industry trials pay \$150 or nothing at all.

This discrepancy between non-industry, assumed to be mostly academic, and industry review fees mainly reflects the academic sponsor's capacity to pay. The pharmaceutical industry believes that the current fees for review should be based on cost recovery and aligned with the actual service provided.

Clinical trials benefit institutions by enhancing a culture of critical assessment and discovery, of rigorous training of graduate and post-graduate personnel, and of close patient involvement. They provide the opportunity for:

- industry to collaborate with academia to explore novel uses of medications through pilot studies;
- seeking greater knowledge about the use of medications which are more specifically applicable to medical practice in Australia; and
- investigating the optimum use of the medicines which employs a broader range of translational medicine capabilities than exists within the companies alone.

It is broadly acknowledged throughout the sector, that institutions and industry play a complementary role in conducting clinical trials. Clinical trial units have been critically dependent on funding from industry sponsored clinical trials to ensure the viability of their wider research programs.

This issue of appropriate fee for service also applies to other elements of conducting clinical trials in hospitals such as pharmacy fees, site initiation costs and institutional overheads. There needs to be a consistent national approach to the development of charges for conducting clinical trials in Australia, to ensure that the fees reflect the cost incurred in the actual activity in accordance with cost recovery principles. However, it must be noted that Australia's position as a lower cost centre for conducting clinical trials has been seriously eroded in recent years. If we are to continue to attract global trials to Australia, a key objective of any cost measurement initiative will be to ensure trial costs are contained and/or reduced over time.

The issue of costing activities in Australian hospitals was noted in the 2009 Productivity Commission report, *Public and Private Hospitals*. The report found that 'existing cost data is not comparable between hospitals due to inconsistent collection methods and missing information'¹⁶. The National Health Reform Plan provides initiatives to develop efficient pricing for hospital services, based on activity based costing methods. These proposed reforms could better align costs of conducting clinical trials, thereby enabling the development of consistent and fair national approaches to cost-recovery by all trial sponsors. It is expected that the NHR pricing will show that the Australian environment is competitive against North America and Western Europe. The NHR should indicate to institutions that they need to be more efficient, provide greater support for research and the importance of attracting clinical research to Australia.

¹⁶ The Productivity Commission, 2009, *Public and Private Hospitals*

TO PROVIDE FOR COST RECOVERY OF EFFICIENT CLINICAL TRIALS

To further accelerate clinical trial start-up in Australia by reducing uncertainty around clinical trial costs in the public health system for trial sponsors and public institutions, the CTAG proposes the following to address the issues above:

Recommendation C: That the Parliamentary Secretaries for Health and Innovation propose to the AHMAC, that a table of standard costs associated with conducting clinical trials be developed for all trial sponsors in alignment with Australian Government health reform initiatives as they are introduced. This table should include:

- standard items developed by the NHMRC by July 2011;
- the efficient cost of the service reflecting the actual activity in accordance with cost recovery principles and determined by the proposed independent hospital pricing authority; and
- a reasonable additional payment to support the thirty calendar day timeframe for efficient ethics and research governance review outlined in Recommendation A.

4. CLINICAL TRIALS AND E-HEALTH

The use of electronic means to capture, store and analyse clinical trials data provides the opportunity to greatly improve the conduct of clinical trials. In addition, the development of systems for trial information management in Australia must keep pace with reforms and directions in the major trial locations, particularly the US and Europe.

Many nations have embarked on national e-Health programs; large-scale examples include the Infoway effort in Canada and Connecting for Health in the UK. Several programs have the goal of an electronic health record (EHR) as a core part of their program delivery. To reach this outcome, many infrastructure and business process changes need to take place to ensure clinical information is appropriately collected, stored, distributed, and applied. The mechanics of how these outcomes are achieved differ across the range of healthcare delivery models and through other drivers. They range from centralised record sharing services managed by national authorities through to independent record repositories managed by individual clinical service providers. These may then collect into regional health initiatives. The politics of access control, consent, and ownership will determine how much clinical collaboration can be supported by any system.

Australia actively engages in the international e-health standards community through Standards Australia IT14 as well as directly with the International Organisation for Standardisation, Health Level Seven® (HL7®) and IHTSDO (Snomed CT). Adherence to international standards ensures stronger alignment of e-health requirements with international software products and practises, allows for less Australian-specific customisation, increases the healthcare benefit and minimises e-health investment. Standards alignment is a core part of Australia's national e-health strategy.

There is considerable international effort and collaboration to develop standards and systems to incorporate clinical data into EHR that can be used for clinical trials. The ultimate goal for Australia in the e-health clinical trials field would be to develop a seamless interface from a nationally accepted, whole of healthcare, clinical data collection system to any clinical trials database, without the need for double data entry. There are many efficiencies for clinical trials operation that can be gained from this in terms of improved data quality, ease and speed of access to data (lowering costs of managing trials), and improved information on population health; opening opportunities for better targeting of research, feasibility and patient recruitment.

AUSTRALIAN E-HEALTH PROGRAM

The National E-Health Transition Authority (NEHTA) was established in 2005 by the Australian Government and state and territory governments to progress e-Health in Australia. NEHTA's work to date has focused on the key foundations required to support the safe and secure exchange of health information across Australia. This includes the foundation work needed on identifiers, authentication, common language, and technical standards.

Endorsed by Health Ministers in October 2008, the National e-Health Strategy sets out a roadmap over a ten year time-frame for further national e-Health development and implementation by the Commonwealth and states and territories.

While NEHTA does not currently have a specific remit to incorporate clinical trials information needs into the e-health system, to some extent, harmonisation with international standards will assist this process. However, there are key initiatives which could be pursued by NEHTA which will ensure that clinical trials needs are designed into the national system, thereby providing much improved efficiencies in trial conduct.

CHALLENGES AND OPPORTUNITIES FOR AUSTRALIA

E-Health and improved ICT systems will be key enablers to enhance the performance of the Australian clinical trials sector. Functions which ICT/e-Health can deliver, and barriers that will need to be addressed, are analysed in the following sections.

TRANSPARENCY OF TRIAL CONDUCT

Research data must always be verifiable against the source data and this requires secure access to electronic medical records held in institutions, whether or not they are part of a national system. Traditionally, patients gave consent for review of their medical records for this purpose, and trial monitors reviewed (paper) patient records in considerable detail. However, access is not always provided to monitors, auditors and regulators for EHR.

Consistent policies and functionality (eg the ability to be able to restrict EHR access for sponsor monitors to their trial patients) need to be adopted across institutions and jurisdictions to enable access to trial patients' EHR (and only those records) for clinical trial monitors and auditors. Once access is established, policies and system capability should be extended to enable remote monitoring of electronic medical records in order to validate trial data.

Remote access for monitoring and verifying clinical trials data against the electronic source records offers Australia tremendous scope for radically improving efficiency of monitoring trials. The standard frequency of on-site (in person) trial monitoring every four to six weeks across Australia's vast geography has resulted in significant travel time and cost. Remote monitoring could see this travel frequency significantly reduced, resulting in tremendous time and cost savings. There are the logistics of data transfer and privacy hurdles that will need to be overcome to make remote access possible, including the incorporation of privacy enhancing technologies and mechanisms.

CLINICAL TRIALS PORTAL/PLATFORM OF APPROVED TRIALS

A national electronic system or a more robust distributed service delivering the same required outcome could be developed to provide visibility for all stakeholders across clinical trials in Australia.

This national system (e.g. a portal) could include information on the phase of the trial, trial outline, approval date, sites involved and the expected enrolment period, as well as the lead or coordinating investigator contact information. It could also include information on the end-date for recruitment and information on the number of patients recruited (the dataset should be validated with potential users – consumers, investigators and sponsors). Such data could be used:

- to provide a full understanding of the breadth and depth of clinical research in Australia (currently almost impossible);
- by sponsors to identify sites with expertise and capacity/ability to recruit in particular therapeutic areas;
- by institutions that are seeking to join an existing trial that has received ethical approval;
- by researchers to identify research programs 'synergistic' with their own aims; and
- by patients, or their health practitioners, to identify research programs relevant to their needs (this objective is discussed in more detail in the next section on patient recruitment).

EFFICIENT COLLECTION AND USE OF HIGH QUALITY DATA

Future developments in e-health offer the promise of linking clinical trials data collection systems with clinical patient care systems to improve efficiency and data quality. Currently, there are major interfacing issues with the current myriad of electronic systems which have been implemented at a hospital, state and national level. This would need to be done incrementally. The initial steps should highlight the need to place software that can be developed into the clinical area in the trial space.

A detailed operational investigation of trial and clinical information systems should be undertaken to determine if there are systems which already permit data transfer. This should involve clinical and trial staff in real-time assessment of system development, maintenance and risk-management issues. This investigation would result in the development of a set of functional specifications for the class of software which serves the trial and clinical operations community.

Over the medium term, these specifications should lead to the development of a software project to adapt existing software for Australian use in trials and clinical operations. This would incorporate the principles of automatic patient selection and data collection standards, single data entry with inclusion of primary data sources, and secure case report form (CRF) reporting. Reporting would also include CFR21 Part 11¹⁷ compliance, full audit trails, and the ability of researchers to track all changes with signatures.

The formal description of data standards for Australian trial specification should be developed in association with, and maintained by NEHTA. These standards should relate to trial description and work flow, and aid in the searching of appropriate trials to match patient parameters.

At present, consent to use clinical trial data is done on a per-trial basis. Consent forms have some common terms but a large number of proprietary terms still exist. This means that the person explaining the consent for the trial (often a clinician) must know and understand a (potentially) large number of different and proprietary consent frameworks. The proprietary nature of this also means that data custodians rarely know exactly how the data collected can be used. This will be further complicated if the clinical trial and its functional systems are linked. This means that providing data from clinical systems to trial managers and vice-versa is far more complicated than it need be. An option is to define a standard consent framework, which could provide a small number of standard permission levels for data use (from completely private through to completely accessible), with patients and trial managers determining which level of permission is applied to their data.

Given the challenges involved in meeting the needs of multiple customers, trial designs and meeting international standards for multiple data management platforms, it would be necessary to refer this activity to an appropriate expert group. In the case of sponsored trials, data capture is driven by the sponsors of the trials who must consider data capture from multiple sites and countries. Also a wider review is required into the existing ICT infrastructure supporting clinical trials. This review would consider opportunities for improved functionality and interoperability to support trial approval and management. It would also progress policy initiatives, privacy compliance, and the design and specification of a seamless interface between the clinical and operational health system.

¹⁷ Viewed March 2010, <http://www.21cfrpart11.com>

THE POTENTIAL FOR INFORMING HEALTH RESEARCH POLICY

Clinical data, whether collected for trial or clinical purposes, should be available for additional research projects and policy development with due consideration to privacy principles. Data should also be traceable and conform to consistent meta-data as well as data standards. Storage architecture should be consistent with this aim.

In addition, documentation of the provenance (i.e. traceability of data, documentation of appropriate meta-data for the data, documentation of the quality assurance/quality control processes that may have changed the raw data set) of the data asset is important for journal publications and re-use of the data set by other researchers.

If, as envisioned, the future of trial systems is a seamless interface into the clinical system and the whole operational health system, without double entry, then the boundaries between clinical and clinical trials data use start to blur. It will often be desirable to allow data collected for one use to provide information for another, with the appropriate privacy considerations. Whether this data originates from a trial system and is then ported to a clinical system or vice versa, the data collected will be indistinguishable by source.

The same considerations relate to data collected for clinical trials, where early stage trial data, for example academic studies, may be re-used to inform later stage or related trials, if appropriately handled and collected. This is a trend internationally, with the aim of accelerating studies and bringing effective treatments forward more rapidly. For example, when studying less common ailments, it is often difficult to recruit sufficient numbers of patients for trials, and thus trials may extend over years. If this data is not collected in an appropriate fashion to allow its re-use (for example by employing proper audit trails, strong data management practices and adequate ethical consents) then later clinical trials may need to re-run the initial studies, considerably delaying the implementation of treatments.

TO ENSURE THAT CLINICAL TRIALS CAN TAKE ADVANTAGE OF THE DEVELOPING E-HEALTH SYSTEM

In recognition of the continuing implementation of electronic records in Australia and of international developments in e-health that will facilitate integration of clinical trials and clinical patient care data systems, CTAG recommends:

Recommendation D: That the Parliamentary Secretaries for Health and Innovation propose to AHMAC that it:

- introduce policy and/or systems that allow access (both on-site and remote) by clinical trial monitors and auditors to the electronic health records of clinical trial participants; and
- request National E-Health Transition Authority (NEHTA) and state and territory governments to make the clinical research system a key consideration when designing, developing and implementing e-health standards, specifications, strategies, frameworks, systems and programs. To that end NEHTA should:
 - explicitly examine its potential role in the development of specifications for interfaces between provider systems, trial registry and referral services; and
 - convene a forum of relevant stakeholders to examine existing ICT infrastructure supporting clinical trials and consider opportunities for improved functionality and interoperability to support trial approval, management and patient recruitment.

5. PROMOTING CLINICAL TRIALS INFORMATION AND IMPROVING PATIENT RECRUITMENT

A recent clinical trials survey showed that 90 per cent of industry sponsored trials in Australia experience recruitment delays¹⁸. Furthermore, while Australian recruitment rates for Phase I, II and IV studies compare favourably with global averages, Australia is less competitive at recruiting for Phase III studies, which constitute the single largest volume of studies and patients. Developing more efficient and effective recruitment strategies is considered essential for the ongoing success of the Australian clinical trials sector.

Australia's strong and inclusive public health system removes motivation for some patients to enrol in clinical trials in order to receive adequate healthcare. However, there are many factors that contribute to Australia's slow recruitment rates, including:

- a relatively small and geographically dispersed population;
- insufficient support of trials amongst hospitals and health professionals (partly due to a lack of recognition that trials are an integral part of delivering best clinical practice);
- little national co-ordination of recruitment within many therapeutic areas;
- a lack of public and health practitioner awareness about clinical trials, their potential benefits and what clinical trials are ongoing;
- lengthy and complicated Patient Information and Consent Forms; and
- a lack of GP engagement with clinical research or assistance in recruiting patients for clinical trials.

CURRENT PATIENT RECRUITMENT METHODS

Predominately, the investigator will recruit from their patient pool or patient referrals. An investigator may also promote the trial to colleagues in their hospital or at associated hospitals, or to colleagues in private practice in order to gain referrals of suitable patients. When patients that are normally treated in a primary care setting are required, sponsors/investigators may advertise trials in local media and/or hold information sessions with local GPs. Extensive media advertising is not commonly used as participating ethics committees have different requirements and as such the required screening of respondents for these committees is often not cost effective.

Research coordinators and study coordinators may also assist with patient recruitment through various means including reviewing clinical medical records.

¹⁸ Pharmaceuticals Industry Council, 2009, 2009, Report on the Pharmaceuticals Industry Council R&D Taskforce 4th Forum Clinical Research in Crisis – Preparing Ourselves for Survival, viewed March 2010, <http://www.pharmacouncil.com.au/resources.php> [p 39]

WEBSITES THAT PROVIDE CLINICAL TRIALS INFORMATION

There are many clinical trials databases around the globe on which investigators can register their clinical trials. These have become increasingly utilized recently with the revised Declaration of Helsinki, released in October 2008, stating that "Every clinical trial must be registered in a publicly accessible data base before recruitment of the first subject." The intention of this Declaration is a means of establishing transparency in clinical research.

Commonly used clinical trials registries are:

- **Australian New Zealand Clinical Trials Registry (ANZCTR)**
Established in 2005, the ANZCTR is a publicly accessible on-line register of clinical trials being undertaken in Australia and New Zealand. The ANZCTR is hosted by the Clinical Trials Centre at the University of Sydney and funded by the NHMRC. The trial information that is available through ANZCTR is more detailed than that published for the CTN/CTX schemes. The ANZCTR includes Australian trials and overseas trials involving Australian patients. These are from the full spectrum of therapeutic areas including trials of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. However it is not a comprehensive listing. Many global trials that involve Australian sites are not registered on the ANZCTR but rather elsewhere, since the Helsinki Declaration pertaining to trial registries merely requires a trial to be registered somewhere.
- **The US Clinicaltrials.gov registry**, where the majority of industry-sponsored clinical trials are registered, was the first international open-access clinical trials registry, established in 1997 by the United States National Institutes of Health (NIH) and the United States Food and Drug Administration (US FDA). Pharmaceutical companies that operate in Australia tend to register on www.clinicaltrials.gov for global trials involving Australia.
- **The World Health Organisation International Clinical Trials Registry Platform** (WHO ICTRP) is another source of Australian clinical trials information, albeit incomplete. The ICTRP has a search portal that interrogates several registries including www.clinicaltrials.gov and the ANZCTR.

This fragmented approach to clinical trials registration casts doubt over which sources of information can reliably show Australian activity at either a detailed individual trial level or at an aggregated clinical trials sector level. Trends and proportions may be detected using multiple registry information but these would be with a number of qualifications.

Presently, aggregate data from the TGA CTN/CTX schemes are supplied upon request to external stakeholders, for example, governments or industry associations. The CTN/CTX schemes use a paper based lodgement system and any data that is retrieved needs to be performed manually. Data that has been supplied is:

- New Trial Protocols Notified by State;
- New Protocols Notified by Phase; and
- Trial Sites Notified by State.

In late 2009, the TGA started supplying data on the number of trials by phase and the number of new trial sites by state and territory. Stakeholders are very supportive of the TGA providing this new information. If this data was published on a central website or portal then this could significantly reduce the time spent by TGA staff in responding to requests for information.

Presently, there is very little reliable and accurate information which enables us to determine the contribution that clinical trials make in terms of healthcare, innovation, investment and productivity to Australia. Figures that do exist are superficial and cover only a single element of trials such as pharmaceutical company investment.

TO IMPROVE PATIENT RECRUITMENT

Clinical trial registries could be used to increase patient self-referral, however, registry information is designed to meet study publication requirements, rather than the needs of self referral. As an initial step towards assisting the public to access information regarding clinical trials and improve patient recruitment, existing sources of information should be able to be searched by consumers in an easy and convenient manner. The CTAG recommends the following:

Recommendation E: That the NHMRC develop a consumer-friendly web portal that includes information on all current clinical trials in Australia. The portal would:

- provide access to Australian clinical trial information that is contained on searchable registries such as the Australian New Zealand Clinical Trials Register (ANZCTR), clinicaltrials.gov and the International Clinical Trials Registry Platform run by the World Health Organisation (WHO);
- link, with permission, to existing patient databases of consumer advocacy groups and existing clinical trial networks; and
- improve regular reporting on clinical trial activity in Australia.

NATIONAL COORDINATION

In general, there has been limited crossover between the private sector and research networks and public facilities in regards to clinical trial conduct, especially into the general practice setting. National coordination of recruitment activities has been limited because Australia's health and research infrastructure is usually focused within therapeutic areas or regional (area health or jurisdictional) boundaries. However, without national coordination, recruitment rates will continue to be slow.

In consideration of the factors contributing to Australia's difficulty in recruiting high numbers of patients quickly to clinical trials the following section outlines ways to address these factors.

IMPROVING PATIENT RECRUITMENT THROUGH A CONSUMER ORIENTATED CLINICAL TRIALS PORTAL

As noted above, there is no comprehensive register of clinical trials that reliably assists interested patients and health practitioners in locating suitable trials in Australia. In addition, a number of the more widely used registries are based overseas where there is no Australian control over their ongoing accessibility.

An Australian based consumer-orientated clinical trials portal would be a key resource for the provision and dissemination of information on clinical trials. This comprehensive portal should have the following features:

- the ability to list all clinical trials being conducted in Australia and be accessible to the general public, investigators, academic institutions, hospitals and industry bodies;
- be easily searchable and provide a lay summary of each clinical trial;
- the ability for members of the public to register their interest for trials in a particular therapeutic area, thereby allowing sites to quickly identify potential subjects;
- an investigator database where potential investigators could register their interest in trials in a particular therapeutic area; and
- information about clinical trial outcomes.

This should be implemented in such a way as to complement and build critical mass with other relevant and emerging initiatives. While there are several highly effective examples of Australian clinical trials networks with excellent recruitment rates, a systematic approach to consumer participation is lacking across all disease states. A consumer oriented portal highlighting the benefits of clinical trial participation and current participation opportunities is likely to improve recruitment systematically and enhance Australia's competitiveness. Such a portal will leverage the ongoing efforts of many consumer advocacy groups to generate an integrated hub for clinical trials recruitment. In addition to improving Australia's competitiveness in terms of attracting sponsored research, enhanced clinical trial activity generated through this consumer based mechanism will have spin off benefits including the development of a larger skills base in evidence based clinical research, critical to the translation of local pharmaceutical and biotechnological innovations.

TO IMPROVE PATIENT RECRUITMENT

As a further step towards assisting the public to access information regarding clinical trials and improve patient recruitment, an Australian based, comprehensive and searchable clinical trials portal should be investigated. The CTAG recommends the following:

Recommendation F: That the NHMRC and DIISR investigate by July 2011 the feasibility of creating a comprehensive and searchable web portal, similar to the US-based clinicaltrials.gov that would include (but not be limited to) the following functions:

- the capacity for potential participants and health practitioners to register their interest in future clinical trials, where those that have registered would be notified of new activity in their nominated therapeutic area(s);
- allow monitoring of trial outcomes;
- require all clinical trials conducted in Australia to be registered on it; and
- improve regular reporting on clinical trial activity in Australia.

INVOLVEMENT OF GPs TO BOOST PATIENT RECRUITMENT

GPs play a significant function in clinical research as they have the ability to refer their patients onto clinical trials. To date, the development of trial centres and/or general practice networks to facilitate access to patients in the primary care setting have been relatively limited and transient in Australia. The few GP clinics that can function as clinical trial sites are located within practice based research networks (PBRNs), which are mostly funded through the Primary Health Care Research Evaluation and Development strategy of the Australian Government. PBRNs aim to build research capacity in primary health care by developing and supporting GP research so that they are enabled to conduct long-term research collaborations. Anecdotal evidence suggests there are some private GP practice groups that are establishing clinical trial capacity.

A further opportunity for utilising GPs in the clinical trial recruitment process is through the use of existing GP software to prompt the GP to suggest to relevant patients suitable clinical trial opportunities. This could involve a pop-up box when accessing certain information through the software. Patients could be asked to contact a nearby trial site to discuss the trial and consider if they wish to participate. Such a system would provide opportunities for patients, primary healthcare providers and researchers to be aware of trial opportunities.

TO IMPROVE PATIENT RECRUITMENT

To assist with patient recruitment by providing information about clinical trials through GPs, CTAG proposes the following:

Recommendation G: The forum of relevant stakeholders (identified under the second dot point of Recommendation D) examine ways in which existing general practitioner software can be used to enhance patient recruitment.

PROMOTING CLINICAL TRIALS INFORMATION AND BENEFITS

Australia has a highly educated public which is broadly supportive of research but tends to have a negative perception of clinical trials due to a lack of understanding. Also, key to improving recruitment is a paradigm shift in healthcare policy and practice where clinical research provides the best evidence of the effectiveness of new and existing treatments¹⁹ and therefore clinical research needs to be integrated into standard clinical practice.

Presently, the Australian general public has a low awareness and understanding of the benefits of clinical trials. A targeted clinical trials awareness campaign would aim to improve recruitment rates in Australia by promoting access to information, the value of trials and dispelling concerns.

¹⁹ National health and Medical Research Council, 1999, *A guide to the development, implementation and evaluation of clinical practice guidelines*.

IMPROVE THE PATIENT CONSENT PROCESS

The consent process is critical to recruitment. Information provided in the Participant Information and Consent Form (PICF) needs to be presented in easy-to-understand language. The length of the PICF can be a deterrent to potential participants and consideration could be given to separating the information pertaining to the study in question from the more general clinical trials information.

TO IMPROVE PATIENT RECRUITMENT

As a means to improve participation in clinical trials in Australia, the public's understanding of clinical trials and their benefits need to be improved. CTAG recommends the following strategy:

Recommendation H: That DIISR work with DoHA, health consumer groups and other stakeholders to develop and distribute by July 2011, consumer information through GP and specialist offices, designed to encourage consumers to talk to their doctors about suitable clinical trial options.

6. SUPPORTING ENHANCED CLINICAL TRIALS NETWORKS

Clinical trials networks have been established within specific therapeutic areas primarily to facilitate collaboration among key clinical researchers. These networks may be national or state-based and predominantly support investigator-initiated trials.

Clinical trials networks provide a wide range of support to investigators and clinicians through the whole life cycle of a trial, including:

- trial feasibility, design and protocol development;
- funding for trials administration and infrastructure, for example, key trial staff, office costs, IT support and travel to collaborative group meetings;
- education and training for trials personnel;
- central data management; and
- statistical analysis of data.

The challenge for current trial networks is to ensure that there is capacity to participate in current and new clinical trials and that access to appropriate patient groups is facilitated to support recruitment. Capacity can be built by amalgamating co-operative groups across Australia, and through the provision of funding to support network overheads. Well coordinated, inclusive clinical research networks are an important means to:

- ensure that unmet health needs or priorities are being addressed;
- contribute to the development of cross jurisdictional approval mechanisms and
- support the needs of academic and industry studies.

BETTER SUPPORT FOR NETWORKS

Discipline-based trial networks could be enhanced by:

- supporting and developing discipline-based trials networks or groups charged with developing clinical trials programs in high priority health areas;
- ensuring there are sufficient trained staff and eligible patients available for rapid and successful Australian trials of high priority;
- determining the feasibility of supporting existing networks and groups by enhancing their activities to improve their coverage to a national level; and
- varying existing networks to support new networks or groups.

TO FACILITATE BETTER NATIONAL COORDINATION AND GREATER COLLABORATION ACROSS CLINICAL TRIALS NETWORKS

To help facilitate the conduct of clinical trials and enhance levels of participation in these trials greater coordination of research is required. In order to strengthen collaboration between networks, the CTAG recommends:

Recommendation I: That greater support for clinical trial networks in priority health areas be provided through the NHMRC by:

- identifying the networks that exist in Australia by July 2011; and
- facilitating national coordination and encouraging collaboration across academia, clinical medicine and industry.

7. ONGOING COMMITMENT TO PROGRESSING CLINICAL TRIAL ISSUES

The CTAG considered a wide range of options to improve the clinical trials operating environment in Australia. The recommendations developed by the CTAG will provide greater momentum in the key clinical trial areas of ethics and research governance review, e-health, patient recruitment and national co-ordination of clinical trials networks.

In addition, the following recommendations will progress key issues that have not yet been covered:

Recommendation J: That DIISR collate available material about the value and performance of Australian clinical trials.

Recommendation K: That the Pharmaceutical Industry Working Group (PIWG) becomes a mechanism for relevant stakeholders to continue to have input into clinical trials policy and co-ordinate implementation of improvements by:

- NHMRC regularly reporting the progress and success of the HoMER initiative; and
- periodically reviewing the progress of the above recommendations.

As a package, these recommendations aim to build upon the actions already taken by the government and other stakeholders that are already benefiting clinical trials, for example the HoMER initiative.

The significant number of submissions and the large number of people who have taken the time to contribute to this report is a strong indication of the importance of the clinical trials sector in Australia. It is a wide reaching sector with many different and disparate stakeholders that all make their own contribution. The ongoing and valuable contributions from all levels of government, researchers, industry, hospitals and patients to the clinical trials environment will ensure that clinical trials continue to contribute to the health and well being of Australia.

ABBREVIATIONS and ACRONYMS

AHMAC	Australian Health Ministers' Advisory Committee
AHMC	Australian Health Ministers' Conference
ANZCTR	Australian New Zealand Clinical Trials Register
AuRED	Australian Research Ethics Database
COAG	Council of Australian Governments
CTAG	Clinical Trials Action Group
CTN	Clinical Trial Notification (Scheme)
CTRA	Clinical Trial Research Agreement
CTX	Clinical Trial Exemption (Scheme)
DIISR	Department of Innovation, Industry, Science and Research
DoHA	Department of Health and Ageing
EHR	Electronic Health Record
GCP	Good Clinical Practice
GP	General Practitioner
HoMER	Harmonisation of Multi-Centre Ethical Review initiative
HREC	Human Research Ethics Committee
ICH	International Conference on Harmonisation
ICT	Information and Communication Technologies
NEAF	National Ethics Application Form
NEHTA	National E-Health Transition Authority
NHHRC	National Health and Hospitals Reform Commission
NHMRC	National Health and Medical Research Council
NHR	National Health Reform
NS2007	2007 National Statement on the Ethical Conduct of Research involving Humans
PICF	Participant Information and Consent Form
PISG	Pharmaceuticals Industry Strategy Group
PIWG	Pharmaceuticals Industry Working Group
TGA	Therapeutic Goods Administration

APPENDIX 1:

MEMBERSHIP OF THE REFERENCE GROUPS

1. Developing a Clinical Trials Roadmap

Chair: Professor Jim Bishop	Australian Government Chief Medical Officer, Department of Health and Ageing
Mr Andrew Way	CEO, Alfred Health
Professor Garry Jennings	Director, Baker IDI Heart and Diabetes Institute
Professor Michael Millward	Head of Cancer Trials, Western Australian Institute for Medical Research
Dr Amanda Caples	Director, Science & Technology Programs, VIC Government
Dr Mark Jacobs	Director, Office of Biotechnology and Therapeutic Medicines and Devices, Department of Employment, Economic Development and Innovation, QLD Government
Professor Paul Gatenby	Director of Research, TCH Professor of Immunology, ACT Government
Dr Peter Satterthwaite	Director Medical Services and Education, Royal Darwin Hospital
Dr Jurgen Michaelis	CEO, Bio Innovation SA, SA Government
Ms Anne O'Neill	A/g Director Medical Research, Office for Science and Medical Research, NSW Government
Ms Janelle Barnes	A/g Manager, Life Sciences Industry Development, WA Department of Commerce, WA Government
Dr Craig White	Chief Health Officer, TAS Government
Dr Carlo Maccarrone	Head of Clinical Research in Australasia, GlaxoSmithKline
Mr Andrew Giddy	CEO, Nucleus Network

2. Developing Key Performance Measures for Clinical Trials

Chair: Professor Richard Fox	Director of Research, St Vincent's Hospital, Melbourne
Dr John Primrose	Medical Advisor, Pharmaceutical Benefits Division, Department of Health and Ageing
Professor John Simes	Director, NHMRC Clinical Trials Centre
Professor Philip Aylward	SA Elected Member of the Board, Department of Cardiovascular Medicine, Flinders Medical Centre
Professor Ric Day	Director, Clinical Pharmacology and Toxicology, St Vincent's Hospital Sydney

Dr Jane Jacobs	Principal Advisor, Research Ethics & Governance Unit, Office of Health and Medical Research Centre for Healthcare Improvement, Queensland Health, QLD Government
Dr Brendan Murphy	CEO, Austin Health and Chairman, Victorian Health Service Management Innovation Council
Ms Deborah Monk	Director of Innovation and Industry Policy, Medicines Australia

3. Ensuring the Rapid Uptake of Streamlined Ethics, Scientific and Governance Review Processes

Chair: Professor John Funder	Senior Fellow, Prince Henry's Institute of Medical Research
Ms Ellen Kittson	Director, Research Integrity, National Health and Medical Research Council
Dr Jo Mitchell	Associate Director, Research, Ethics and Public Health Training Branch, NSW Health
Dr Jane Jacobs	Principal Advisor , Research Ethics & Governance Unit, Office of Health and Medical Research, Centre for Healthcare Improvement, Queensland Health,
Mr Bill Karanatsios	Public Healthcare Program Victorian Managed Insurance Authority
Dr Catherine Bourgeois	Formerly, Director, NSW Clinical Trials Business Development Centre
Ms Helen Aunedi	Senior Manager of Regional Operations & Compliance, Baxter Healthcare
Mr Terry Clout	CEO, South East Sydney and Illawarra Area Health Service, NSW Health
Ms Imelda Lynch	CEO, Bellberry Limited
Dr Nikolajs Zeps	Manager, Research Laboratory, St John of God Hospital, Perth

4. Strategies to Increase Patient Recruitment for Clinical Trials

Chair: Mr John Stubbs	Executive Officer, Cancer Voices Australia
Professor Geoffrey Donnan	Director, National Stroke Research Institute
Professor Stephen Ackland	Senior Staff Specialist, Department of Medical Oncology, Calvary Mater Newcastle Hospital
Dr Jeff Karrasch	CEO, Australian Clinical Research Organisation

Professor Noel Cranswick	Director, Clinical Pharmacology and the Australian Paediatric Pharmacology Research Unit, Murdoch Children's Research Institute and Royal Children's Hospital, Melbourne
Dr Munro Neville	Director, Pretium
Dr David Lloyd	Business Operations Manager Trident Clinical Research
Assoc. Professor Vlado Perkovic	The George Institute for International Health, The University of Sydney
Mr Mitch Kirkman	Manager, Process, Training, Quality, Clinical Development, Novartis Pharmaceuticals Pty Ltd

5. Developing an ICT Strategic Plan for Clinical Trials

Chair: Ms Carol Bennett	Executive Director, Consumers Health Forum of Australia Inc
Dr Marisa Petersen	CEO, Association of Regulatory and Clinical Scientists (ARCS)
Dr Phil Gurney	CEO, Australian E-Health Research Centre
Professor John Seymour	Chair, Haematology Service, Peter MacCallum Cancer Institute
Ms Ann Larkins	Clinical Trials Manager, Barwon Health
Ms Liz Forman	Assistant Secretary, e-Health Branch, Department of Health and Ageing
Dr Andy Bond	Chief Architect, National e-Health Transition Authority (NeHTA)
Assoc. Professor Andrew Miller	Senior Clinical Lecturer, Dermatology, Australian National University

APPENDIX 2

LIST OF SUBMISSIONS

1. Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT), Professor Ray Morris, President
2. Australian Cancer Trials Online, Dr Rachael Dear, Project Coordinator
3. AusBiotech Ltd, Dr Anna Lavelle, CEO
4. Burnet Institute
5. Cancer Institute NSW
6. Cancer Trials Australia Laboratory, Dr John Barlow, Director of Laboratory Services
7. Cancer Voices NSW Inc, Sally Crossing AM, Chair
8. Clinical Oncological Society of Australia (COSA), Professor Bruce Mann, President and Professor Stephen Ackland, COSA Enabling Grant Chair, jointly with Cancer Council of Australia, Professor Ian Olver, Chief Executive Officer
9. Clinical Trials Connect, Christine Veljanoski and Mary Pym, Directors
10. Consumers Health Forum of Australia, Carol Bennett, Executive Director
11. Denis Strangman
12. Eli Lilly Australia Pty Limited, Dr Deon Gouws, Medical Director
13. Evado Pty Ltd, Ross Anderson and Jennie Anderson
14. GBS Venture Partners Ltd, Joshua Funder
15. Genzyme Australasia Pty. Ltd
16. Geoff Bloom, Partner, HWL Ebsworth Lawyers
17. GlaxoSmithKline
18. Haematology Clinical Trials Group, Royal Adelaide Hospital, Sr Simon McRae, Consultant Haematologist and Che To, Manager
19. Health Services Commissioner, Department of Health, Victoria (Ms Beth Wilson)
20. Hunter New England Health Clinical Cancer Research Trials Network
21. Infonetica Australia, Ainsley Martlew, General Manager
22. Dr Janelle Bowden
23. Juvenile Diabetes Research Foundation, Mr Mike Wilson, Chief Executive Officer
24. Linear Clinical Research Ltd, Cameron Johnson, General Manager
25. Linear Clinical Research, Western Australian Institute for Medical Research
26. Medical Technology Association of Australia
27. Medicines Australia, Brendan Shaw, Chief Executive
28. Merck, Sharp & Dohme (Australia) Pty Limited, Claire Henderson, Associate Research Director ANZ
29. Monash Faculty of Medicine, Nursing and Health Sciences, J McNeil and S Wesselingh
30. Murdoch Children's Research Institute

31. National Association of People Living with HIV/AIDS (NAPWA)
32. National Association of Testing Authorities (NATA), Jane King, R&D Program Manager
33. National Breast and Ovarian Cancer Centre, Dr Helen Zorbas, Chief Executive Officer
34. National Breast Cancer Foundation, Sue Carrick, Head National Research Strategy
35. NHMRC Clinical Trials Centre
36. NSW Department of Health
37. Office of the Privacy Commissioner
38. Royal Australian College of General Practitioners (RACGP)
39. Royal Australasian College of Physicians (RACP), Dr Yvonne Luxford, Manager, Policy and Advocacy
40. Research Australia Ltd, Dr Gabby Fennessy, Manager, Strategy and Policy (contact)
41. Roche Products Pty Limited
42. Rosalind Stott, Study Coordinator, Department of Radiology, Sir Charles Gairdner Hospital
43. Royal Perth Hospital, Professor Peter Leedman, Director of Research, Research Administration and Governance
44. Paul Scuffham, Professor of Health Economics, School of Medicine, Griffith University, Queensland
45. The George Institute for International Health and The Chalmers Centre for Partnerships in Healthcare Innovation, Professor Stephen MacMahon, Principal Director, Associate Professor Vlado Perkovic, Executive Director and Dr Alan Cass, Senior Director
46. Treatments for Children Research Network - Australia
47. Unimutual, Harry Rosenthal, General Manager, Risk Management
48. University of Sydney
49. Western Australian Institute for Medical Research, Professor Peter Leedman, Deputy Director

Five submissions were made in-confidence which increases the total number of submissions to 54.