

## CLINICAL TRIALS ACTION GROUP (CTAG) RECOMMENDATIONS – STATUS TABLE

### CTAG Recommendation

#### 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<sup>1</sup>;
  - 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.

#### **ON TRACK**

NHMRC is currently working with jurisdictions to provide advice to AHMAC, via the Clinical, Technical, Ethical Principal Committee (CTEPC), regarding implementing the HoMER initiative. NHMRC has implemented tools to support the single ethical review which are available at: <http://hrep.nhmrc.gov.au>. The 'Research Governance Handbook: Guidance for the national approach to single ethical review' has been released and will be available from <http://hrep.nhmrc.gov.au/>. Guidance on monitoring is currently being considered by the HoMER Reference Group. The HoMER Reference Group is considering the best way in which to introduce the sixty calendar day maximum timeframe for ethics review, including a 'stop clock' function, as part of the certification criteria which will take effect by January 2012. Key performance indicators (KPIs) are also being developed. Other aspects of Recommendation A are currently being considered by the CTAG Co-ordination Group.

#### **Responsibility**

NHMRC have taken responsibility for reporting to AHMAC when jurisdictions have agreed on specifics of HoMER, however DoHA will assist in preparing relevant input for consideration by AHMAC regarding introducing relevant policies and progress (3<sup>rd</sup> and 4<sup>th</sup> dot points).

<sup>1</sup> Note: The issue of the 30 calendar timeframe has been the subject of discussion and deliberation at PIWG and the CTAG co-ordination group. It has been agreed that there are issues around the 30 day Recommendation that may be unworkable at the current time. As a consequence, this part of Recommendation A is not being actively pursued at this time.

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### **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.

### **ON TRACK**

Professor Warwick Anderson, CEO of the NHMRC, has written to Deputy Vice-Chancellors of Research (DVCR) in Universities across Australia to inform them of the benefits of adopting the national approach to single ethical review, highlighting the reforms as outlined in Recommendation A of the CTAG report and to invite their cooperation. It was agreed at a CTAG Coordination Group meeting that a DVCR representative be invited to a subsequent meeting as well as a representative from Australian Private Hospitals Association.

A key achievement of the HoMER initiative is the commencement of the NHMRC's National Certification Scheme for the ethical review processes of institutions. To date, 37 institutions have been certified under the Scheme. The Human Research Ethics Web Portal was released on 1 July 2011 and contains information on the national approach to single ethical review.

### **Responsibility**

NHMRC have taken responsibility for reporting to AHMAC when jurisdictions have agreed on specifics of HoMER, however DIISR will prepare a Minute for joint signature (with DoHA) by the Parliamentary Secretaries to inform and support Universities and Private Hospitals regarding the implementation of HoMER.

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### **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<sup>2</sup>.

### **ON TRACK**

The NHMRC developed a table of standards items for public consultation, which was open for comment until 12 August 2011. NHMRC are currently compiling all comments from this consultation process into a summary paper. This paper will be used by the Transition Office (TO), via the Department of Health and Ageing (DoHA), to identify possible costing options and will report back to the CTAG Coordination Group. The TO have advised that they are able to provide assistance at the macro level through an activity based costing approach using the Diagnosis-Related Group (DRG) system to classify 'products' that a hospital provides. Ideally the TO will be able to cost the principal diagnosis and the principal procedure and add an administration cost according to the location of the trial, to come up with an average cost of an individual clinical trial.

Members of the CTAG Co-ordination group will investigate whether there is an opportunity to review trial establishment costs independently of the hospital pricing process. The CTAG Co-ordination group will be seeking advice from the Research and Development Taskforce of the Pharmaceuticals Industry Council.

### **Responsibility**

DoHA reported to AHMAC at their September 2011 meeting, requesting Health Ministers note the progress made on this recommendation and to consider the implementation of consistent policies. State and Territory members noted the progress of the CTAG recommendations and agreed to support and encourage progress within their jurisdictions.

<sup>2</sup> Note: The issue of the 30 calendar timeframe has been the subject of discussion and deliberation at PIWG and the CTAG co-ordination group. It has been agreed that there are issues around the 30 day Recommendation that may be unworkable at the current time. As a consequence, this part of Recommendation A is not being actively pursued at this time.

## CLINICAL TRIALS ACTION GROUP (CTAG) RECOMMENDATIONS – STATUS TABLE

### 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.

### ON TRACK

Issues identified for this recommendation include; enabling better interfacing between existing commercial software and eHealth network had not been designed, that this recommendation needs to reflect the sensitivity required towards States and Territories as they have already expended money on their current IT systems, that States would need to be confident in the fact that they can provide information and it will be kept safe and used for specified purposes only, the logistics of data transfer and privacy hurdles, interfacing issues with the current hospital electronic systems and agreement on nationalised consent forms. These issues would all ultimately be overcome to allow for the development of a set of functional specifications for the software that serves the trial and clinical operations community.

NEHTA joined the CTAG Co-ordination group after the first meeting. Their contribution ensures an awareness of Clinical Trials and associated high level requirements, including interoperability principles and emerging architectural designs relevant to eHealth. The design of the Personally Controlled Electronic Health Record (PCEHR) system, including the summary health records, event summaries and the indexing function, supports utilisation of eHealth infrastructure for secondary uses such as clinical research. Patients participating in clinical trials will be able to give permission for trial staff to access the patient's PCEHR, and trial staff will be able to add information to the patient's record, provided participation requirements are met. Additional latent capacity in the PCEHR system for secondary uses needs to be further investigated by DoHA in relation to policy frameworks for the management of research proposals and the conduct of research in terms of governance and technical interoperability.

NEHTA and eHealth Branch are organising a workshop of clinicians, including industry, to inform the development of the PCEHR operations. This recommendation is progressing in alignment with Australian Government health reform initiatives as they are introduced.

### **Responsibility**

DoHA reported to AHMAC at their September 2011 meeting, requesting Health Ministers to note the progress made on this recommendation and seek jurisdictional agreement to adopt and apply consistent policies to systems as they are introduced, to help achieve benefits including improved access in rural and remote regions. State and Territory members noted the progress of the CTAG recommendations and agreed to support and encourage progress within their jurisdictions.

## CLINICAL TRIALS ACTION GROUP (CTAG) RECOMMENDATIONS – STATUS TABLE

### 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 Organization (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.

### ON TRACK

NHMRC funds the ANZCTR and has met with them to progress the requirements of this recommendation. NHMRC have discussed patient involvement in health and medical research at a recent meeting of its Consumer Engagement Forum. They will work with this group and the Consumers Health Forum, to encourage linkage.

### Responsibility

Progress relies on the feasibility study as part of Recommendation F. DIISR and NHMRC are responsible for progressing this recommendation.

### 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.

### ON TRACK

DIISR commissioned the Australian E-Health Research Centre (AEHRC) to undertake the study into a *comprehensive and searchable web portal*. AEHRC is a joint venture between CSIRO And the Queensland Government. The study approach is to look at the changing technological landscape and identify opportunities for collaboration between patients, patient and trial networks, investigators, clinicians and other health providers through a central portal, of which the underpinning infrastructure is a complete registry of Australian clinical trials. A Steering Group was formed consisting of members from DIISR, TGA, NHMRC, DoHA, Qld and WA Health Departments and NEHTA. It is planned that the clinical trials portal will integrate with key aspects of enabling eHealth infrastructure including the PCEHR for patient recruitment. A draft of the feasibility study is currently being finalised. DIISR's Science and Infrastructure Division (which administers the Translating Health Discovery funding and allocated \$770,000 (GST incl) to redevelop clinical trials registration) has confirmed that the registry is able to be input into the interactive portal.

### Responsibility

DIISR and NHMRC are responsible for progressing this recommendation.

## CLINICAL TRIALS ACTION GROUP (CTAG) RECOMMENDATIONS – STATUS TABLE

### **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.

### **NO LONGER APPLICABLE**

The implementation of this Recommendation will be incorporated into the scope of Recommendations D, E and F.

### **Responsibility**

This recommendation is no longer applicable but will be reported on by DIISR as part of completing related recommendations.

### **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.

### **ON TRACK**

DIISR recently funded two separate activities under this recommendation, details as follows:

1. Clinical Trials Connect (CTC) has completed an **Industry Information Series** in Melbourne and Sydney to encourage consumers to participate in trials. These sessions showcased web-based patient recruitment methods and highlight the advantages of this technology for improving patient recruitment. CTC submitted an evaluation of the series' effectiveness on 31 August 2011 to inform future initiatives in this area.
2. Consumers Health Forum of Australia (CHF) **Clinical Trials factsheet** - CHF developed a factsheet to encourage consumers to talk to their doctors about suitable clinical trial options. The factsheet was distributed at the Joint Medicines Policy Conference on 30 August 2011 and is currently placed on the CHF and DIISR websites. DIISR are working on the development of a communication strategy for the CTAG Coordination Groups feedback, considering other options for informing consumers on clinical trials.

CHF received feedback on the factsheet from the Therapeutic Goods Industry Consultative Committee at its September meeting and will be undertaking an evaluation to assess consumer views on the value of the factsheet, whether it meets their information needs and whether it helps them to understand clinical trials.

### **Responsibility**

DIISR is exploring further options for distributing the factsheet and is continuing development of the communication strategy with DoHA and other stakeholders.

## CLINICAL TRIALS ACTION GROUP (CTAG) RECOMMENDATIONS – STATUS TABLE

### 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.

### ON TRACK

NHMRC supports a number of networks and registries through the National Health Research Enabling Capabilities Grants. NHMRC developed a list of clinical trial networks which was available for comment from their website: [http://www.nhmrc.gov.au/health\\_ethics/clinical-trials-action-group.htm](http://www.nhmrc.gov.au/health_ethics/clinical-trials-action-group.htm). They are currently finalising the list which will be placed on their website. A link to the NHMRC website was incorporated into the CHF Clinical Trials Factsheet (Recommendation H) and DIISR will give an overview of the Strategic Research Infrastructure Roadmap to look at how patient networks could benefit from the Roadmap initiatives.

### Responsibility

NHMRC is responsible for progressing this recommendation.

### Recommendation J

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

### ON TRACK

DIISR has undertaken an analysis of existing available metrics, and has been working with Medicines Australia on a pilot survey to obtain key value metrics (investment, employment etc) for privately sponsored trials. This survey may be extended to publicly sponsored trials. DIISR is progressing a proposal to utilise the TGA Clinical Trial Notification Scheme to collect metrics on ethics and governance approval timeliness.

### Responsibility

DIISR is responsible for progressing this recommendation.

### 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.

### ON TRACK

DoHA, DIISR and NHMRC all have representatives on PIWG and will continue to report the progress and success of the implementation of all CTAG recommendations.

### Responsibility

DIISR is responsible for progressing this recommendation and reported to PIWG at the 14 November 2011 meeting.