



Australian Government

Clinical Trials Action Group

Discussion Paper Five

**Developing an Information and Communications Technology
(ICT) Strategic Plan for Clinical Trials**

November 2009

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The Government is seeking feedback and comments on options outlined in this paper. The options have not received Government approval and are not law. Feedback and comments received will help to inform the Government's proposed approach on the way forward.

Making a submission:

Submissions on this paper are requested by: Friday, 12 February 2010

Submissions can be sent to:

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Developing an Information and Communications Technology (ICT) strategic plan for clinical trials

Purpose - The development of a Clinical Trials Information and Communications Technology (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.

Background

Potential scope for e-Health in Clinical Trials

e-Health is the electronic collection, management, use, storage and sharing of healthcare information.¹ The following section outlines five key areas where e-Health could be of substantial benefit to the clinical trials operating environment:

- a) *Trial feasibility and patient recruitment:* State and territory governments are progressively implementing electronic patient record systems. Searching these records would assist in establishing the feasibility of conducting a clinical trial in Australia, and give a potential means of consent based patient recruitment. Privacy issues would need to be worked through, with guidance sought from the Privacy Commissioner on the application of the *Privacy Act 1988* and its recently proposed reforms. The design of the e-Health patient record system should also be considered, to quote Peter Fleming, CEO of the National e-Health Transition Authority (NeHTA) (*The Australian*, 13 October 2009):

'The key here is what architecture we will end up with for an e-Health record, and there has only been minimal work on that front because the Council of Australian Governments has not yet approved the business case for electronic health records.'

- b) *Remote monitoring of clinical trials:* To assist in the verification of clinical trial data for use in global regulatory processes, the pharmaceuticals industry seeks remote access to the electronic records of patients that are enrolled in trials (as recommended by the Pharmaceuticals Industry Strategy Group final report, released in January 2009). This would dramatically reduce trial operation costs for multi-centre trials, by reducing the travel costs and time involved in clinical trial monitoring.

Remote monitoring of patient records by hospital staff, with secure data transfer, is already an established practice in many hospitals. However, remote access for industry monitors is a novel proposal. A clear national policy priority within the health system to implement new workplace practices for trial sponsor data monitoring would greatly facilitate industry efforts to introduce this significant innovation. Concerns over privacy issues can be readily addressed by obtaining the full written consent from the patient for industry to monitor access to the patients' entire medical record as a condition of clinical trial enrolment. This has been standard practice for more than twenty years. The only change to this arrangement is that the access will be to electronic records from the monitor's office instead of access to the hospital paper records in the hospital.

Recent efforts by industry to access patient records remotely have met difficulties related to the design of some databases, as the design allows them access to all patient records, not just those patients on the trial. This issue could be potentially resolved with advice from the

¹ NeHTA Strategic Plan, October 2009, p2

relevant privacy authorities, outlining the safeguards required that would enable trial monitors to comply with the privacy regulations.

- c) *Trial approval*: an important component of the National Health and Medical Research Council's (NHMRC's) Harmonisation of Multi-centre Ethics Review (HoMER) project (for background information on HoMER see **Attachment 5A**) is the development of ICT tools to facilitate faster trial approval, with particular focus on information sharing practices to enable more efficient multi-centre ethical review approvals. To inform this work, NHMRC released their *Information Sharing Report* on 31 March 2009², which outlined current HREC information sharing practices.

It has also been suggested that the Clinical Trials Notification Scheme (CTN), which is currently a paper-based process, could implement electronic lodgement with electronic signatures. This simple initiative could reduce the approval process for clinical trials by weeks.

- d) *Management of clinical trials* – Compliance with international standards for drug registration involves a heavy administrative effort in clinical trial management. This applies to ongoing trial conduct and associated record keeping and also in initial approval (both ethical and governance reviews). There is currently no systematic effort to ensure interoperability of data systems across the operation of a clinical trial, let alone integrating these systems with hospital medical records management. Many efficiencies could be gained through building on ethics and governance approval data capture to better manage the trial approval process, as well as better coordinate the day to day management of the trial at a trial site level, in order to facilitate improved management of patients and trial logistics. An integrated system would facilitate faster trial start-up, greater efficiency at trial sites without increased resource commitment, improved quality, faster performance and enable more accurate project budgeting. This would in turn assist trial sponsors to demonstrate improved global competitiveness to global decision makers when considering various destinations for clinical trials.
- e) *Longer term monitoring of patients*: Areas of uncertainty for the Pharmaceutical Benefits Advisory Committee (PBAC) can occur when the length of follow-up of trial participants is less than the expected duration of treatment, or expected duration of health impacts overall. Additionally, the outcomes measured in the trial might not be the patient-relevant final outcomes of treatment. In order to improve the available information, especially in terms of post-marketing evidence development, it is suggested that the proposal to allow easier electronic access to participant files be extended to allow ongoing access to the participants' medical files following trial termination. This will allow researchers to follow up on longer term hospitalisation end points, in addition to relying on shorter term surrogate outcomes of uncertain validity. As there is increased data linkage under the e-Health agenda, this concept could be greatly expanded to promote greater relevance of trial results whilst retaining a robust scientific methodology.

Are there any other benefits that e-Health could bring to Australian clinical trials considering international approaches?
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² HoMER Information Sharing Report (p. 3)

Current government e-Health initiatives

There have been numerous e-Health government initiatives and products that have addressed a need for some aspect of clinical trial activities across Australia and globally (for some examples see **Attachment 5B**). With the exception of the HoMER information sharing initiative for trial approval, there is no co-ordinated effort for existing e-Health solutions for clinical trials across Australia. However, the governments across Australia are working towards developing a national e-Health system.

The National e-Health Strategy endorsed by Health Ministers in December 2008 outlines the *e-Health Implementation Roadmap* for developing the governance, foundations, solutions and adoption processes required for implementing e-Health in Australia. The National e-Health Transition Authority (NeHTA) has been developing the building blocks for a national e-Health platform, including the development of data standards to enable effective information exchange (for background information on NeHTA see **Attachment 5C**).

The National Health and Hospitals Reform Commission (NHHRC) Final Report of June 2009, recommendations 115-123 relate to the implementation of e-Health, and include: the introduction of personal healthcare identifiers by July 2010; a personal electronic health record by 2012, with supporting privacy legislation; a national broadband network; and Australian Government responsibility for the development of national policy and open technical standards by 2011-12.

At this stage it is uncertain to what extent the needs of clinical trials will be incorporated in the future e-Health initiatives.

Development of a clinical trials ICT plan

The purpose of a Clinical Trials ICT Strategic Plan would include (but not be limited to):

- a review of the information management needs and systems currently in place or planned for use in Australian clinical trial units;
- a review of the various initiatives underway through the National e-Health Strategy and hospital reform processes to improve access to patient information by clinical trial sponsors (both industry and institutions);
- a review of the available IT systems and their potential application to Australian trial units;
- a plan for implementing best practice information management by Australian clinical trials units; and
- an opportunity to identify other opportunities to leverage ICT solutions to improve timelines for trial activities or improve the efficiency of trials in Australia (e.g. “e-CTN” concept mentioned above).

The Action Group would need to decide:

- the plan’s scope - which clinical trials units would be included (would they encompass independent research institutes and private hospitals); and
- the method of developing the plan – details of how the reviews should be undertaken; (e.g., is a ‘process review and systems analysis’ required), where and how to obtain the necessary expertise; the required resources.

HoMER background

Taken from http://www.nhmrc.gov.au/health_ethics/homer/index.htm

Overview

In 2006, the Australian Health Ministers Advisory Council (AHMAC) directed the National Health and Medical Research Council (NHMRC) to facilitate the development and implementation of a national system where the single ethical review of a Human Research Ethics Committee (HREC) would be recognised by all institutions participating in a collaborative research project. By having a single ethical review outcome accepted by collaborating institutions, protection of human participants would be maintained while delays due to the current practice of seeking multiple ethical reviews would be mitigated and timelines for research start-up and results would be shortened.

The 2007 joint NHMRC/Australian Research Council/Australian Vice-Chancellors Committee National Statement on Ethical Conduct in Human Research (the National Statement) guides institutions to eliminate unnecessary duplication of ethical review processes (Chapter 5.3).

Several States have formal systems for streamlining ethical review processes in public health organisations. Other jurisdictions have more informal arrangements operating as agreements of acceptance between institutions in the private and public sector and between public health organisations and universities.

AHMAC's initiative directed that the existing and planned State and Territory systems should be 'harmonised' such that collaborative research across jurisdictional borders would be subject only to a single ethical review.

The benefits of adopting a national and formal approach to single ethical review are many:

- The amount of time from ethical review application to research start-up is shortened with the resultant savings in human and monetary resources;
- Australia's attractiveness as a place for international investment in commercial sponsored clinical trials is enhanced;
- Public confidence in the rigour of Australia's system of ethical review of human research is increased due to the standardisation of ethical review processes; and
- The roles and responsibilities of the researcher, the institution, the HREC and other key stakeholders in the conduct of multi-centre research are transparent and consistent.

The uptake of the national approach for single ethical review will respect institutional autonomy to determine whether research should be conducted at a given site. Advice received from a HREC undertaking the single ethical review will not replace the need for local institutional decision making on matters of research governance.

The HoMER Model

The model for implementing single ethical review is not complex. The national approach for single ethical review is based on five simple principles:

- Efficiency – agreed timeframes for processes and procedures are adopted in all jurisdictional systems;

- Authority – the single ethical review of a multi-centre research proposal is accepted by institutions without re-review by their institutional HREC;
- Respect – the national approach accommodates the differences in jurisdictional statutory and administrative frameworks and institutional arrangements;
- Verifiable – the capacity of the HREC carrying out the single ethical review is subject to independent verification; and
- Compliance – multi-centre single ethical review meets the requirements of the National Statement to protect human research participants as well as relevant jurisdictional statutory and administrative frameworks.

The HoMER model is designed to deliver three key outcomes:

- Trust building between institutions and their HRECs;
- Information sharing to enable single ethical review across jurisdictions; and
- A better understanding of the ethical review of multi-centre research.

HoMER tools

Single ethical review is supported by a suite of tools which will enable delivery of the key outcomes. Under the HoMER model, existing State and Territory systems of streamlined ethical review use in-common policies, processes, forms and guidance.

The ‘tools’ that enable institutions to utilise a single ethical review for their collaborative research are:

- In-common policies;
- In-common processes;
- Standardised forms; and
- Guidance.

e-Health Case Studies – Australian and International

A range of software and hardware solutions already exist on the international market, such as SigmaSoft International's DMSys[®], a data management software package for clinical trials (www.sigmasoftintl.com); DZS Software Solutions's ClinPlus[®] Clinical Trial Management System (CTMS) (www.clinplus.com); Evado Clinical Trials Software (www.evado.com.au) and Microsoft's Health Vault (www.healthvault.com).

According to Robert R Goodwin of Pfizer Inc., the company has been working with Oracle to investigate electronic data capture (EDC) and remote data capture (RDC) for clinical trials.³ The Danish pharmaceuticals company LEO Pharma is also using Oracle RDC. Data collected ranges from patient medical histories, medication dosages and laboratory results, to measurements of how the patient is responding to treatments, including any adverse events. Implementation of this system has improved data integrity, data quality, has reduced overall costs and has improved faster regulatory approvals. LEO Pharma claims that by going paperless, the time between when the study finished until the data was available has been reduced from 6 to 12 weeks down to 2 weeks.⁴

Evado Clinical Trials Software is providing clinical trials software to a Malaysian non-government organisation for a cancer prevention program in low income areas. The company updated its clinical trial software to include a "trial management" module, which will allow trial managers to electronically track patient visit scheduling and integrate budgeting functions into the clinical trial software. The new module was developed in response to requests from Asian customers who needed to improve the management of their trials. The company believes the system will deliver significant productivity savings when compared to manual methods of tracking patient visits.⁵

The Cancer Institute NSW Research Division is in the process of implementing InfoEd, a software solution to manage the operations of the Clinical Research Ethics Committee. With the expanding NSW Cancer Trials Network, the Cancer Institute NSW will also implement this software package for the management of the NSW Cancer Trials Network. InfoEd will be made available to all clinical trial units funded through the Network for the management of all clinical trials related activity.⁶

Complete e-Health soft and hardware packages are also being developed and are already being trialled in the United Kingdom, the United States and Germany. InterComponentWare AG (ICW), a German software developer, has been working on e-Health software for a number of years and has been contracted by the German health fund AOK Plus to develop and implement a functioning e-Health system that complies with strict data management, data security and privacy laws. This system can communicate between health funds for reconciliation purposes; store and transfer personal health and other data and can handle remote monitoring of patients via the internet. The German system complies with practically all of NEHTA's requirements. The fund has created an open source software foundation so that the software can be expanded or modified to suit specific requirements.

³ eClinical Visions; Remote data Capture: Acquisition & Analysis
(http://www.oracle.com/industries/life_sciences/pdfs/life-sciences-remote-data-capture-wp.pdf)

⁴ Oracle Case Study LEO Pharma

⁵ BiotechnologyNews.net, 22 October 2009, 'Malaysian cancer study to use Evado software'

⁶ http://www.cancerinstitute.org.au/cancer_inst/research/pdf/2007-10-13_clinical-trials-nsw-cancer-trials-network-key-elements-document.PDF

Bulgaria and a selected number of US health providers have signed contracts with ICW to provide e-Health systems to their specific requirements.

In the United Kingdom, Cerner has been actively involved in implementing their *Millennium*® e-Health software (<http://cerner.com>) which includes patient databases, patient management, medical records management and referral systems.⁷

⁷ http://cerner.com/public/Cerner_2.asp?id=28962

NeHTA background

NeHTA (National e-Health Transition Authority) is a not-for-profit company established by the Australian, State and Territory governments in 2005 to develop better ways of electronically collecting and securely exchanging health information. As a collaborative vehicle, NeHTA has been assigned responsibility for a number of related projects, all aimed at establishing the foundations for the widespread and rapid adoption of electronic health (e-Health) across the Australian health sector.

e-Health is the electronic collection, management, use, storage and sharing of healthcare information. This information can include individual items such as test results, discharge summaries, vaccination history, medication history and diagnoses, to comprehensive medical records which keep all of this information about a person in one place. The governments of Australia recognise that e-Health and an Individual Electronic Health Record (IEHR) service are vital to the achievement of major health reform in the next decade.

e-Health systems that can securely and efficiently exchange data can significantly improve how important clinical and administrative information is communicated between healthcare providers⁸.

⁸ NeHTA Strategic Plan, October 2009, p2