



## **Report on the 2007 Forum: An Update on a National Approach to Clinical Trials**

**1 March 2007  
Rydges Capital Hill, Canberra**

**Sponsor:  
Pharmaceuticals and Biotechnology Branch  
Department of Industry, Tourism and Resources**

**Organising Committee:  
Pharmaceuticals Industry Council R&D Taskforce**

**Forum Logistics:  
Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical  
Industry Ltd (ARCS Australia)**

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## **Executive Summary**

The Pharmaceuticals Industry Council (PIC) R&D Taskforce (RDTF) 2007 Forum – An Update on a National Approach to Clinical Trials, sponsored by the Australian Department of Industry, Tourism and Resources (DITR), was held in Canberra on 1 March 2007. Its aim was to update stakeholders on the many initiatives underway to streamline the approval and conduct of clinical trials in Australia. PIC is a peak industry body with membership and support from Medicines Australia, AusBiotech and Generic Medicines Industry Association. Its goal is to ensure the growth and development of Australia's pharmaceuticals industry. DITR is also represented on PIC.

In welcoming the 160 attendees from industry, Commonwealth and State Government departments of health and industry/state development, researchers and consumer representatives, Michael Schwager, General Manager, Pharmaceuticals and Biotechnology Branch in DITR, drew attention to the Australian Government's support for the pharmaceutical and medical devices industries through both the Pharmaceuticals Industry Action Agenda and Medical Devices Industry Action Agenda, the targeted Pharmaceuticals Partnerships Program (P<sup>3</sup>) and other general industry programs.

The opening session focused on the activities aimed at reducing timelines for clinical trial approvals. The update on implementing a nationally harmonised system of scientific and ethics review of multi-centre research through the Australian Health Ministers' Advisory Council (AHMAC) showed that good progress has been made. At its October 2006 meeting, AHMAC tasked the National Health and Medical Research Council (NHMRC) with implementing the national system of co-ordinated scientific and ethical review. Leadership from NHMRC is critical to the success of a national approach. NHMRC is commissioning a consultant to prepare an implementation plan for such a system, to be available by 30 July 2007, and is establishing a coordinating body within its structure. NHMRC also announced that the revised NHMRC National Statement on Ethical Conduct in Research Involving Humans is due for release in May 2007 and pointed out that it emphasises the need to avoid duplication in ethical review.

Representatives from both NSW and Victorian State Health Departments presented their plans for implementation of slightly different systems of streamlined review, but both involve a single scientific and ethics review for multi-centre studies. All the States indicated that they have made varying degrees of progress towards establishing systems for single scientific and ethical review of multi-centre clinical research. All these approaches are based on a separation of scientific and ethical review from research governance processes. In summary:

- Tasmania has had a system for single ethical review in place since 2005
- NSW will implement its system of single scientific and ethical review using lead ethics committees in July/August 2007
- Victoria plans to have its centralised system of scientific and ethical review in place towards the end of 2007 or early in 2008
- Queensland is currently conducting a pilot of a mutual acceptance model
- WA is trialling a mutual acceptance model through the Sir Charles Gairdner Hospital
- SA is reviewing the current review of multi-centre research and an options paper for streamlined approval of multi-centre trials is being prepared.

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All the States indicated that they supported cross-jurisdictional recognition, once obstacles (especially insurance and indemnity) were resolved.

Concern was expressed by a number of industry stakeholders about the potential for institutions to mitigate against timeline benefits of a streamlined single ethical and scientific review process. The view was expressed that local institutions will need to be expeditious in their research governance review of the project and not attempt to use their research governance role inappropriately (i.e. as a de facto second ethical review). Stakeholders felt that it was critical that institutions be effectively educated on their roles and responsibilities under the new approach by the relevant State Health Department and NHMRC communication.

Additional initiatives being supported by the RDTF making progress include:

- The development of a standard form of contract between sponsors and institutions (model Australian Clinical Trial Research Agreement) for clinical trials, which should be completed by the third quarter of 2007, to reduce duplication of paper work. It was negotiated between Medicines Australia, on behalf of industry sponsors, and NSW, Victoria and Queensland State Health Departments
- Ongoing consultation on a process to make Serious Adverse Event reporting to ethics committees more rational and meaningful, as well as more efficient

The update on the work of the RDTF through its Workgroups, with involvement from a broad range of stakeholders, on other factors (quality, value, capacity) influencing global investment decision making for clinical trials indicated progress on:

- The creation of a competency based development program for clinical trials staff in institutions and industry, as well as an accreditation qualification, to continuously improve quality to enhance Australia's reputation as a provider of high quality data
- Development of a more transparent costing model to inform budget negotiations to assist sponsors in bidding for trials in Australia by ensuring Australia continues to be seen to provide value in clinical research
- Increasing patient participation in trials through working with consumer groups to improve the patient information and consent documents to increase Australia's capacity for clinical research

The newly released Australia New Zealand Therapeutic Products Authority (ANZTPA) Consultation Paper on proposals for regulation of clinical trials was discussed and concern was expressed that the requirement that all first in man studies undergo Therapeutic Goods Administration (TGA) review would adversely impact Australia's global competitiveness. It was agreed by all participants that subject/patient safety is paramount. It was also agreed that interested stakeholders would submit an alternative approach to TGA. Such a proposal must not compromise patient safety, but would maintain Australia's global competitiveness in early phase research, which is a significant growth area for research in Australia.

The 2007 Forum was a great success. Overall, there has been significant progress in the last year in moving to a national streamlined system for ethical and scientific review of multi-centre trials in Australia. A number of initiatives are on track to take effect in 2007. There is still much to do to achieve a streamlined national system, which is critical to significantly improve Australia's global

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competitiveness in starting up clinical trials. This is however a complicated task due to the number of stakeholders involved, the federal and state system of government (requiring interjurisdictional agreement for key initiatives to succeed), as well as the current ANZTPA process. The Forum demonstrated a clear willingness by all stakeholders to continue to work together to achieve the outcomes desired, to enhance the environment for clinical research in Australia. Participants were encouraged to ensure that they actively participated in consultations on all the initiatives discussed during the Forum as these opportunities became available.

Anyone interested in volunteering to assist with any of the RDTF Workgroups is encouraged to send an email to [mitch.kirkman@novartis.com](mailto:mitch.kirkman@novartis.com).

## **1. Forum Introduction**

The Pharmaceuticals Industry Council (PIC) R&D Taskforce (RDTF) 2007 Forum – An Update on a National Approach to Clinical Trials, was sponsored by the Australian Department of Industry, Tourism and Resources (DITR) and held in Canberra on 1 March 2007.

The aim of the forum was to update stakeholders on the many initiatives underway to streamline the approval and conduct of clinical trials in Australia. PIC is a peak industry body with membership and support from Medicines Australia, AusBiotech and Generic Medicines Industry Association. Its goal is to ensure the growth and development of Australia's pharmaceuticals industry. DITR is also represented on PIC.

The Forum Chair was Mitch Kirkman, current Chair of the Research & Development Taskforce (RDTF) under the Pharmaceuticals Industry Council. The RDTF was established in 2004 to ensure the environment for clinical trials in Australia is globally competitive. Mitch holds the position of Manager for Process, Training and Quality in the global clinical development group of Novartis Pharmaceuticals Australia Pty Limited.

## **2. Opening Address – Welcome from DITR**

**Michael Schwager**

**General Manager, Pharmaceuticals & Biotechnology Branch  
Department of Industry, Tourism & Resources (DITR)**

Michael Schwager welcomed participants on behalf of the Pharmaceuticals Industry Council, Association of Clinical & Regulatory Scientists and DITR, describing the Forum as a great opportunity to contribute to the future development of the clinical trials industry in Australia and to the work of the Pharmaceuticals and Medical Devices Industries Action Agendas (PIAA & MDIAA) to unlock the value of Australia's world class medical research base. He noted that both of these joint industry and Australian Government initiatives identified R&D as a key element of achieving their ambitious visions and growth targets:

- PIAA vision – "Double Australia's share of the global pharmaceuticals industry by 2012 through the collaborative efforts of the industry, government and research"
- MDIAA vision – "By 2015, Australia will have an internationally competitive medical devices industry, renowned for innovative and cost-effective health outcomes, that provides quality solutions for Australia and the world."

Michael said that Australia's medical research institutions and universities generate a stream of world-class discoveries with commercial potential every year and, as our pharmaceutical and biotech industries mature, Australia is becoming increasingly attractive as an investment location to international partners.

To put the day's proceedings in context, Michael briefly described the outcomes of the Forum held in March 2006. He noted that, at the 2006 Forum, workshop groups discussed ways the

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environment for clinical trials in Australia could be improved under the headings quality, timeliness, value and capacity, the four factors that had been identified as the most important in influencing global investment decision making for clinical trials. The workshop groups had then identified the next key steps to achieving the required outcome in each area.

Michael acknowledged that much has been achieved since the last Forum in March 2006:

- by the PIAA's R&D Taskforce in progressing the outcomes of the 2006 Forum
- by the Australian Health Ministers Advisory Council on a national framework for approval of clinical trials
- by the States on streamlining ethical approval of clinical trials
- on a Standard Clinical Trials Agreement.

However, he also said that we could not afford to be complacent or lose momentum, because there were issues still to be resolved. He noted that this Forum would focus on some of those issues – measures currently being undertaken to address them and what further actions might be needed. He urged participants to continue to keep working together cooperatively to address them.

Michael stated that it was a Government priority, and the Industry Minister Ian Macfarlane has taken a keen interest, in maintaining Australia's attractiveness as a location for conducting clinical trials. Further, the Government had demonstrated its commitment to encouraging an increase in the level of R&D through programs such as the Pharmaceutical Partnerships Program (P<sup>3</sup>), Small Scale Mammalian Cell Facility grant and R&D Tax Concession.

Michael noted that the 2005 benchmarking study by the Economist Intelligence Unit (EIU) found that Australia was the best place in the world to conduct clinical trials. The EIU found that Australia had good quality clinical trial infrastructure, was a cost effective location for clinical research and completed a large percentage of trials on time and on budget. However, Michael also noted that Australia scored less well for the total number of clinical trials being conducted and the total number of trials by phase, even on a per capita basis, and the average time for ethics approval was longer in Australia than for all other countries in the study except India. So there was room for improvement.

Michael said a streamlined national approach to the conduct of clinical trials is important both for the development of viable, competitive pharmaceutical, biotech and medical devices industries and to achieving vision of both the PIAA and MDIAA.

The Australian Government had made a commitment to reduce the regulatory burdens on business and established the Regulation Taskforce, chaired by Gary Banks, to identify actions to address unnecessarily burdensome, complex, redundant or duplicative regulation. The Taskforce report, which was wide ranging and touched on regulation in many areas, was released in January 2006 and the Government response, released in August 2006, accepted in whole or in part the majority of recommendations. Michael commented that implementing its recommendations would help to: improve regulation-making; ensure good performance by regulators; avoid overlap, duplication and inconsistency; and ensure that regulation delivers over time, thereby reducing the time and cost burden of regulatory compliance. He noted the specific recommendations of interest to the pharmaceutical and medical devices industries, agreed to by the Government, included 4.17 and

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4.18 relating to the Australian New Zealand Therapeutic Products Agency (ANZTPA), and 4.19 (3<sup>rd</sup> party conformity assessment) and 4.22 (Health Technology Assessment).

Michael referred specifically to the recently-released consultation document from the TGA and Medsafe on the proposed regulatory framework for clinical trials under ANZTPA. Michael made it clear the Government would always treat safety, efficacy and quality as fundamental and would not shy away from appropriate regulation to achieve this. But he acknowledged industry concerns at a possible increase in regulatory oversight for certain early phase trials. He said it was very important that industry respond and that DITR was keen to get feedback from industry on the likely impact of the proposals and discuss the issues with them.

Michael also said that DITR was always open to industry contact, and wanted to know about and discuss industry's concerns with them and how they might be addressed.

In summary, Michael said that we need to build on the progress already made and get a commitment by the States and industry to work together and with the Australian Government to resolve the outstanding issues in achieving a national approach to clinical trials. He urged participants to make the most of the unique opportunity being offered today to make a solid contribution to the establishment of a national approach to clinical trials in Australia, for the future of their industries.

### 3. Towards a National System of Scientific and Ethics Review of Multi-centre Research

*Objective: Update on NHMRC activities to implement recommendations put forward by AHMAC Working Group Report*

**Jane-Ann Jones**  
**Director Research Ethics, Quality and Regulation Branch**  
**National Health and Medical Research Council (NHMRC)**

Jane-Ann Jones began by describing the context for her presentation. She noted that the *National Statement* provides guidance and encouragement on minimising duplication of ethics review and that the NHMRC has provided additional leadership, advice and encouragement, e.g. via the national research ethics conferences. NHMRC and its Australian Health Ethics Committee (AHEC) had noted the need for stakeholder 'buy-in' on this issue if progress was to be made.

In describing the history of the move towards a national system of scientific and ethics review of multi-centre research, Jane-Ann noted that, in February 2005, an inter-jurisdictional forum, "Towards timely, efficient and effective review of multi-centre clinical trials" had been held and a key principle agreed at the forum was "Every trial is ethically and scientifically reviewed once only, with a single submission point for applications". As a result of that forum, in June 2005, the Australian Health Ministers' Advisory Council (AHMAC) had agreed that "An inter-jurisdictional working group be formed to develop a report for consideration by AHMAC on achieving a streamlined national approach to ethical and scientific review of multi-centre research, while having regard to the initiatives of individual jurisdictions".

Jane-Ann outlined the Terms of Reference for the AHMAC Working Group:

- Assess the current international, national, State and Territory arrangements for the ethical and scientific review of multi-centre research.
- Develop options for a nationally co-ordinated system for the single ethical and scientific review of multi-centre research.
- Present a proposal to AHMAC identifying ways forward.

The Working Group employed a consultancy firm to prepare a report, *A streamlined national approach to scientific and ethics review of multi-centre health and medical research: issues and options*, on its behalf, which was considered by AHMAC at its October 2006 meeting.

AHMAC agreed that a nationally harmonised system of scientific and ethics review of multi-centre research should be established. It also agreed with NHMRC's proposal that the co-ordinating body should be situated within the NHMRC and that the NHMRC would prepare an implementation plan for co-ordinating the nationally harmonised system.

Jane-Ann outlined the action taken by NHMRC following the October 2006 AHMAC decision – an open tender process had been undertaken to secure a consultant to develop the required implementation plan, for consideration by NHMRC. The successful tenderer is Management Effect.

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She advised that a Steering Group will provide advice and direction to the consultant, and that, in developing the implementation plan for consideration by NHMRC, the consultant is required to:

- consult extensively with stakeholders;
- have regard to the report presented to AHMAC from the Working Group; and
- identify the respective roles of the NHMRC and the jurisdictions.

She noted that eight key issues were to be addressed in developing the implementation plan, which is to be provided to NHMRC by 30 July 2007:

1. Liaise with jurisdictions with a view to them identifying HREC(s) in their State/Territory that are able to conduct reviews of cross-jurisdictional, multi-site research.
2. Recommend a system of review and recognition of these identified HRECs.
3. Develop policies and strategies regarding the separation of research governance from research ethics.
4. Develop policies and strategies regarding a national approach to insurance and indemnity.
5. Develop criteria for allocating proposals to these identified HRECs; and a fee-charging policy.
6. Identify respective responsibilities for monitoring of approved research.
7. Develop and implement a national information technology platform to support the national system – must incorporate the National Ethics Application Form.
8. Appeals mechanism.

**The main points to come out of the Q&A session were:**

- In regard to requests for additional consultations by the consultants, e.g. with patient advocacy groups, Jane-Ann advised attendees that it was important to note that the high standard of protection of research participants provided by the current HREC system will be maintained. A national system for streamlining multi-centre research would continue to be based on the requirements of the *National Statement on Ethical Conduct in Research Involving Humans*, and HRECs that form part of the national system will be expected to comply with the *National Statement's* requirements.
- It was agreed that the separation of research governance activities from research ethics is one of the particular challenges to be met if a successful national system is to be implemented.

## 4. Updates on Streamlined Ethical Review for Multi-centre Research

*Objective: Update on progress to implement streamlined multi-centre trial approval in NSW and Victoria*

### 4.1 NSW - Single Ethical Review of Multi-centre Research: Update on Implementation

**Ainsley Martlew**  
**Senior Analyst, Health Research and Ethics Branch**  
**NSW Health**

Ainsley Martlew began her presentation by outlining why NSW Health had decided to implement a system for single ethical and scientific review of multi-centre research:

- Well-recognised need for reform
- Need to improve efficiencies by maximising the use of scarce resources and reducing duplication of effort
- Need to improve effectiveness by improving standards and consistency of review
- Need to improve timeliness by allowing research projects which are ethically acceptable to commence in a more timely manner
- Need to improve capacity to attract quality research activities.

Ainsley then described the key features of the NSW Health model of single review:

- Every research project ethically and scientifically reviewed once only
- Lead HRECs accredited to conduct a single ethical and scientific review on behalf of all sites within NSW Health
- Co-ordinating Principal Investigator (CPI) to choose to which lead HREC to submit multi-centre research project
- HRECs to review ethical and scientific issues only, not matters of research governance
- All NSW Health institutions to recognise the ethical and scientific review undertaken by a lead HREC.

Written notification of the final ethical opinion of the lead HREC should be provided to the CPI within a maximum of 60 calendar days. The 60-day clock will:

- commence on the submission closing date for the meeting at which the application is to be first considered.
- stop while awaiting a response from the CPI to a request by the lead HREC.
- apply to the lead HREC review only. It does not apply to the overall time taken for sites to grant authorisation for the commencement of research.

Ainsley stated that lead HRECs would be accredited, meaning that an assessment would be made of an HREC's ability to meet NSW Health's set performance standards, such that the HREC is accepted as being capable of providing a single ethical and scientific review for the entire public health system. This would engender trust and confidence between all parties and maintain both

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transparency and quality of scientific review. She noted that, as yet, no such system existed in Australia, but would comprise two components – initial accreditation of HRECs which meet the standards and a 12-18 month follow-up by a peer reviewer. Both components would involve the submission of documented evidence. The accreditation standards would be both qualitative and quantitative, and relate to both the ethical and scientific review mechanisms. There would be additional standards for clinical research and health services research.

Ainsley then outlined the role and purpose of the electronic application tracking and management system within the single review context. She said it would enable application tracking, prevent unnecessary duplication of effort, facilitate communication between HRECs and sites, permit some evaluative functions to be performed and provide a feedback mechanism for researchers. She said that, beyond the review of multi-centre research, it could be used for the generation of standard letters, minutes and agendas.

The separation of research governance from ethical and scientific review is crucial to the success of the single-review model because:

- Ethical and scientific review can be undertaken once, however research governance (assessment of clinical trial agreements, insurance and indemnity arrangements, budgets, sign-offs by Department Heads etc) must occur at each site
- HREC approval is just one element to be taken into consideration by the site
- Ultimately, institutions (not their HRECs) are responsible for research governance. HRECs are not resourced or trained to do this
- Only the Chief Executive (or delegate) has the authority to authorise the commencement of research within their institutions.

Ainsley outlined the NSW Health model for research governance. She stated that every site must conduct a site specific assessment (SSA) of the research project, using a standard SSA Form. SSA involves consideration of the suitability of research personnel, departments and services involved, resources required (financial, staff and time commitments), other regulatory considerations (eg. radiation safety, biosafety), clinical trial requirements (e.g. insurance and indemnity, clinical trial agreements) and adherence to site-specific policies in Patient Information Sheets (e.g. use of contraception). Ainsley stressed that both an approved SSA and an approved lead HREC review were required before authorisation could be given to commence research at an institution.

Ainsley noted that, as consultation had been completed, work was now progressing on implementation. Standard operating procedures, standard documentation and a fees policy were being finalised and the IT system was being customised prior to pilot testing. Ainsley said NSW was consulting with Victoria on IT issues, with a view to both States using the same front end. An ICH GCP Focus Group was to be established, the process for independent evaluation finalised and Memorandums of Understanding signed between all parties. Ainsley outlined plans to progress accreditation of lead HRECs – a Selection Panel would be convened in May, followed by a call for Expressions of Interest and an assessment of the applications. The peer-review process is still being finalised.

Ainsley also outlined the roll-out training and education program: three days intensive training would be held for HREC Executive Officers and Research Governance Officers on using the IT system, how to conduct a site-specific assessment etc.; training for researchers, industry and study coordinators would be held on submitting on-line applications, checking the status of applications, submitting site-specific assessment forms etc.

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Ainsley concluded by stating that the NSW Health system for single ethical and scientific review of multi-centre research would go live in July/August this year (2007). In addition, she stressed that NSW Health had not done all of this in isolation – the collaborative effort with the other States (e.g. on the SSA Form) had been very important.

**The main points to come out of the Q&A session were:**

- The lead HREC will be responsible for the review of currently reported serious adverse events, amendments and on-going monitoring. NSW Health is developing a policy to streamline the reporting and review of serious adverse events.
- The lead HREC will be responsible for ethical and scientific review
- The Area Health Services will be responsible for implementing the SSA process – appointing a Research Governance Officer, oversight and resourcing – and there will be a fee for processing site-specific assessments.
- Transitional arrangements are still to be finalised – up to CPI to decide?
- The CPI does not need to come from NSW Health.
- Lead HRECs will be able to set a cap on the number of multi-centre applications received per month
- What happens when a lead HREC does not approve the addition of a new site for a study approved prior to implementation of the single review model is still to be finalised

## ***4.2 Victoria - An Update on a National Approach to Clinical Trials***

**Dr Suzanne Hasthorpe**

**Project Manager, Biotechnology**

**Public Health Branch, Department of Human Services, Victoria**

Suzanne Hasthorpe began by outlining the key features of the Victorian model intended for single ethics review of multi-site trials:

- “At arms length” from Government with an “independent” governance structure (Board-like)
- Centralised ethics committees and sub-committees, with a central secretariat
- Applications linked to a database with electronic communications & administration
- Benchmark – 30 working day approval (~6 weeks)
- Voluntary participation
- Initially review of clinical trials, then extending to all multi-site human research
- Review fees for commercially-sponsored research only

Suzanne commented that the last feature followed from a survey that found that clinical trials accounted for 66.7% of multi-site ethics submissions, epidemiological studies 8.3%, social research 12.5%, population health studies 8.3%, and other 4.2%.

Estimates had been made of future workload and these had been used to decide how many committees might be needed:

- Year 1 – predicted total of 300 applications with approximately 150 commercially sponsored clinical trials. Assuming an optimal level of 10 applications per committee meeting would require three committees, each meeting once per month, on a rotating basis across each month

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- Year 2 – increase in applications, expand to four committees
- Years 3/4 – expand as required to five committees

Suzanne stated that, consistent with the AHMAC principles, ethical review was separated from research governance, with ethical review to be the responsibility of centralised committees and research governance the responsibility of the organisation conducting the research, i.e. “the site” will submit a Site-Specific Assessment (SSA).

The SSA was an assessment of the suitability of the site and the Investigator(s), with consideration of:

- Project and site policies, departments and services involved, suitability of research personnel and training
- Time commitment and resources required of the research team
- Study budget, other financial or material support, administering organisation
- Clinical trial requirements – CTN or CTX, insurance and indemnity
- Other regulatory considerations, e.g. radiation, biosafety
- Recruitment of participants, information and informed consent
- The chain of responsibility for the SSA would be Principal Investigator=>Research Governance Officer=> “Authorised” by the Chief Executive (or delegate)

Suzanne outlined the Standard Operating Procedures (SOPs) for ethical review, firstly, the quality steps and checks:

- Validation of applications before acceptance to review
- Co-ordinating Principal Investigator (CPI) is responsible for submitting a valid application, including a SSA
- “Clock stops” when CPI response is required
- Commencement at other sites is dependent on receipt of a valid SSA or notification, once ethical approval has been decided

Suzanne then described the path followed by a new application:

- Applicant: intention to submit – Notify secretariat (phone); Booking made – reference number, closing date for submission
- Application (+SSA1) on HREC agenda & entered on Research Ethics Database (RED)
- Submit application & 1 original hard copy - signed
- Validation assessment (5 working days)
- Valid application – 30 working day clock starts
- Not valid – void and deleted or valid after discussion & 30 working day clock starts
- Scientific/methodological review
- HREC review

The changes for commercial sponsors identified by Suzanne included:

- Application – NEAF (NHMRC) – but same process for protocol and Investigator’s Brochure
- CTX/CTN schemes – same role for sponsors; forms attached to SSA
- Centralised HREC review includes scientific and technical expert review, e.g. FTIH, Phase 1 trials

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- Costs would include a fee for ethical and scientific review, SSA at each participating site, amendment fee, but no fee for SAEs

and the benefits for sponsors were identified as:

- Central HREC – all correspondence copied to sponsor
- Deal with one HREC only
- Faster review time
- One version of documents
- Standardised documents – Application, SSA, CTA (Medicines Australia model agreement)

The SOPs would provide:

- Comprehensive guide for researchers, sponsors, central administration and central HRECs
- General ethical review procedures
- Procedures for amendments
- Complaints and appeals processes
- Monitoring and reporting – CPI, sponsor and HREC roles

Suzanne concluded by describing what Victoria saw as the critical factors in achieving a national approach to streamlining multi-site clinical trials:

- A coordinating body to support a nationally-harmonised system
- Mutual recognition by all jurisdictions
- Standard forms and consistency of review
- A single ethical review Australia-wide

**The main points to come out of the Q&A session were:**

- HREC responsible for patient information/consent, but some details to be finalised re: SSA
- Mutual recognition with other jurisdictions to be decided at a policy level
- The impact on local ethics committees will be monitored as part of post-implementation evaluation
- No clock on research governance; process can be facilitated by preparing SSA information for submission with the ethics application (NEAF) at the CPI site, with other sites to follow and less work for other sites
- Training and further consultation will occur during the implementation phase

### **4.3 Panel Discussion - Progress Across Australia Towards a National Solution**

*Objective:*

- *Qld, SA, WA, TAS have opportunity comment re State activities and alignment with national solution*
- *What are seen as the key obstacles to a national solution?*
- *How and when can they be overcome?*
- *Questions from the floor?*

**Panel:**

- **NHMRC – Jane-Ann Jones, NHMRC**
- **New South Wales – Ainsley Martlew, NSW Department of Health**
- **Victoria – Suzanne Hasthorpe, Department of Human Services, Victoria**
- **Queensland – Anne Walsh, Queensland Department of Health**
- **Western Australia – Nik Zeps, WA Department of Health**
- **South Australia – Andrew Stanley, SA Department of Health**
- **Tasmania – Murray Shanley, Chair, Tasmanian HREC**

Queensland, WA, SA and Tasmania representatives outlined the activities in their respective States and how these aligned with a national solution.

#### **4.3.1 Queensland**

- Have developed a Mutual Acceptance Model
- Similar to NSW, with a "lead" HREC
- Model being piloted from November 2006 to March 2007
- Main issues to be addressed include resources and workload, developing a "trust" culture, and establishing a database

#### **4.3.2 Western Australia**

- Following the NSW forum in February 2005, conducted a review of the existing system of multi-centre trial review in WA
- Identified that research governance needed to be separated from ethics review
- Sir Charles Gairdner Hospital is the "guinea pig" for implementing a governance unit, so that it can be demonstrated that separation works in practice
- The existing system of reciprocal approval has been tightened up to ensure research governance and monitoring requirements are met
- The WA Dep't of Health is coordinating a multi-centre mutual acceptance scheme that can be voluntarily adopted by the public and private hospitals and universities

#### **4.3.3 South Australia**

- Kick-started by clinicians raising with the Minister, who took it on board
- Similar process to NSW's

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- A retrospective audit should be completed by the end of April – preliminary results indicate that less than 8% of projects are "multi-centre"
- Have found it is better to deal with the institutions, as the HRECs tend to be obstructive
- Once the public hospitals are on board, it will be raised with the Research Vice Chancellors at the universities
- Next steps are to finish the audit and develop an options paper
- All this is occurring in the context of major changes to SA health legislation for the first time in 30 years

#### **4.3.4 Tasmania**

- In 2001, the University of Tasmania and the Department of Health and Human Services signed an agreement to start a process with the eventual aim of one Tasmanian HREC
- In 2005/06, amalgamated the north and south HRECs to form one HREC administered by the Research Office at the University of Tasmania in Hobart with meetings held by Video Link-Up between Hobart and Launceston
- Some difficulties finding appropriate expertise
- In 2007, mandated use of the National Ethics Application Form (NEAF) and recommendation that trial be registered on the national Clinical Trials Register

All four States noted that cross-jurisdictional issues are yet to be addressed.

#### **4.3.5 Discussion**

**Q1:** Which HREC will take the lead? How will the decision be made? What input will consumers have to that decision?

**A:** The National Statement sets out the appropriate expertise required for an assessment – it will be up to NHMRC/AHEC to set the accreditation standards for HRECs.

**Q2:** Legal compliance differs across the jurisdictions. How will HRECs cope?

**A:** This will be included in the SSA.

**Q3:** Will the private system be integrated into the national framework?

**A:** No reason why not.

**Comment from panel:** Whether a top-down or bottom-up approach will be taken is to be considered.

**Q4:** Will Victoria and NSW benchmark to see which system is better?

**A:** No. It is important for each State to implement the model which suits its specific environment, however, both single review models have been designed to meet the same objectives.

**Q5:** When will discontinuities be addressed? Will there be a commitment to do so?

**A:** NHMRC's task is to implement a national system. NSW is working within that and there is no reason why they cannot integrate.

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**Comment from WA:** WA's Research Governance Unit takes into account what approvals have already been granted in the other States. It has only ever held up two applications – insurance and indemnity issues. This area is a minefield.

At the end of the Panel Session, there was a very positive feeling that there is a clear commitment to make progress on the national framework.

## 5. Update on Other Significant Initiatives

*Objective: Update on progress with each topic and allow information sharing with questions/discussion from stakeholders*

### 5.1 Revised NHMRC National Statement, NEAF & AHEC priorities

**Professor Colin Thomson**  
**Chair, Australian Health Ethics Committee (AHEC)**

#### 5.1.1 National Statement Revision

Colin Thomson began his presentation by announcing that the final version of the *National Statement* had been agreed at the AHEC meeting on 27/28 February 2007 and would be presented to the NHMRC Council for approval at its March 2007 meeting. A recommendation that it be published would then be made to the NHMRC CEO. It is a requirement that the revised *National Statement* be tabled in both Houses of Federal Parliament, this would occur in May 2007 and would be followed by a transition period for information, promotion and institutional compliance.

Colin noted that revised *National Statement* had more content than the current Statement:

- A chapter on interventions and therapies, including clinical and non-clinical trials, includes guidance on
  - description of trial phases
  - research merit and integrity
  - justice in participant selection and recruitment
  - risks
  - records
  - respect (for participants)
  - monitoring (specific to clinical trials)
- A new chapter on minimizing duplication of ethical review, is designed to facilitate and not impede other multi-centre initiatives. It provides that
  - Wherever more than one institution is responsible to ensure ethical review of a human research project, each responsible to adopt a review process that eliminates unnecessary duplication.
  - Institutions that regularly have review responsibilities for the same research should agree on a single review body.
  - Further, where an institution relies on ethical review by a body it has not established, it should:
    - (a) identify local circumstances relevant to the ethical review of the research, disclose these to the review body/ies, & provide for their management;
    - (b) exchange relevant information and advice with the review body/ies;
    - (c) not duplicate existing, duly authorised scientific, technological or methodological assessment;

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- (d) establish the roles, if any, the institution and the review body/ies have in monitoring the research;
  - (e) inform participants if the research is discontinued; and
  - (f) adopt any other administrative procedures that will avoid unnecessary duplication of ethical review.
- Where these previous paragraphs apply, researchers should inform the ethical review body that reviews and approves the research:
- (a) of all other sites at which the research will be conducted, and of the name and location of any other body that will conduct an ethical review of the research; and
  - (b) of any previous decisions made about the research by other review bodies (in Australia or elsewhere).

### **5.1.2 National Ethics Application Form (NEAF)**

Colin stated that the NEAF provides for review by one or more HRECs of multi-site and multi-investigator projects and can be found at <http://www.neaf.gov.au/>

Colin noted that there were over 2000 applications on the NEAF database to date. He also advised that the NEAF would be revised in line with the new *National Statement* – it would have the same structure, but there would have to be some changes made to accurately reflect the changed National Statement. Colin invited everyone in the audience to "play" with it, as it was free.

In response to a question that why at present only about 10% of total annual ethics applications were entered on the NEAF, Colin said he did not know but suggested that maybe a cultural shift in ethical review processes was required.

Colin then gave a live demonstration of accessing the NEAF, registering an application, entering information etc. He highlighted the email hotlink on the site for feedback etc and said there was also a phone-in hotline.

### **5.1.3 AHEC Relevant Priorities**

Colin stated that AHEC's priorities are to be developed in the context of the NHMRC Strategic Plan, which is currently with the Minister for approval. He noted that the NHMRC Act requires the CEO to develop a strategic plan including:

- the CEO's assessment of the major health issues that are likely to arise in the current triennium; and
- the manner in which the CEO proposed to perform his functions in dealing with those issues

Further, the Strategic Plan must contain a national strategy for medical research and public health research. Colin also noted that the Strategic Plan (for the period 1 January 2007 – 31 December 2009) was provided, as required, by 31 December 2006.

Colin said that the Strategic Plan reflected a ten-year vision with achievable performance indicators and would establish a small number of key strategic goals supporting the best and most relevant

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health and medical research, advancing the evidence-base for national health policy and a robust ethics framework. The NHMRC's strategic objectives are:

- The best and most relevant research
- Evidence base for health policy and practice
- High ethical standards
- Increased investment (The virtuous cycle)
- To build a better NHMRC

Leading on from the Strategic Plan, AHEC's priorities relevant to the Forum included:

- Carriage of development of national multi-centre ethical review implementation plan
- Revision of National Ethics Application Form (NEAF)(in line with revised NS)
- National program of audience targeted information sessions on NS and NEAF
- Probably from June to October
- National research ethics conference – Melbourne, October 2007

## ***5.2 Model Clinical Trial Agreement***

**Deborah Monk, Medicines Australia (MA)**

Deborah Monk stated that one of the main reasons for the development of a model Clinical Trial Agreement (CTA) was to assist in streamlining ethical review and that it was one of several initiatives to standardise documentation. However, it was recognised that one size will not fit all cases and the CTA has been designed primarily for public health institutions. It was, therefore, planned to extend the model CTA to other situations, including CROs and specialist research centres (e.g. Phase 1 units). She also noted that MA was committed to reviewing the model CTA 12 months after implementation and, in particular, to reviewing the Special Conditions (Schedule 7) where companies may need to seek variations from the standard form.

Deborah outlined the development of the Model CTA, which started within the MA Clinical Working Group, with the first draft based on members' agreements. She said that two rounds of consultation had been held with members, followed by extensive negotiations with the States, which included the NSW Health Ethics Branch and their legal advisers, the VMIA and Department of Human Services and their legal advisers, and Queensland Health and their legal advisers.

Deborah said that, when the final draft CTA had been circulated to members for agreement prior to going to the MA Board for sign-off, some concerns had been expressed. Key issues included:

- Role of the Principal Investigator
- Management of replacement of a Principal Investigator
- Grounds for terminating a trial
- Financial issues
- Precedence of protocol vs. CTA
- How the CTA applies to CROs
- Whether the CTA should require an Institution to hold liability insurance
- Publication policy – consistency with companies' own standard agreements

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- Privacy – Question of necessity of detail

Deborah advised that a meeting had been held with members on 27 February 2007 to discuss those concerns and explain the reasoning behind the provisions in the draft CTA. Additional information had been provided and changes to the draft model CTA identified.

Deborah said that it was planned to send a further revised model CTA to the State representatives as soon as possible, prior to a meeting to discuss the changes in mid-March. If agreement was reached, the model CTA would be presented to the MA Board for sign-off at its April meeting. An explanatory paper would be prepared to assist the Board in making an informed decision. The model CTA would then be implemented.

**The main points to come out of the Q&A session were:**

- The PI will not be a party to the CTA, but will certify the he/she has seen and will abide by the terms etc
- Inconsistencies between the protocol and CTA should be avoided. Should such a situation arise, the differences should be contained in Schedule 7 of the CTA and the CTA will take precedence
- Use of the CTA will not be mandated
- Extension to CROs is planned – it might be a 2- or 3-way agreement depending on the circumstances. No timeline for its development was provided.

### ***5.3 A Model for Adverse Event Reporting to and Review by HRECs***

**Dr Nik Zeps**

**Radiation Oncology, Sir Charles Gairdner Hospital, WA**

Nik Zeps began by presenting the background to the work on adverse event (AE) reporting and review in Australia, namely that one of the objectives in implementing a national streamlined ethical review system was to decrease HREC workloads. He noted that serious AE (SAE) management by HRECs contributed to that workload.

The RDTF had therefore hosted a meeting in September 2006, with the objective of developing a more rational process for HREC review of SAEs. It was attended by a wide range of stakeholders, including from the AHMAC Working Group, the Commonwealth (TGA, NHMRC AHEC), HRECs/Scientific committees (NSW SSAS, Peter MacCallum Cancer Centre), States Health (NSW, WA), researchers (NSW Cancer Institute, Cancer Trials Australia), and Industry (Novartis, Boehringer Ingelheim, MSD, GSK, Quintiles).

Nik summarised the issues discussed:

- Volume of SUSARs/SAEs to HRECs
- No uniformity with Sponsors in level of AE info supplied
  - some all SAEs, some only unexpected
- Responsibilities in regulations vs. guidelines unclear
  - National Statement says “that may effect the conduct of trial” – all SAEs?
  - Regulations global and local

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- IND re AEs to IRBs
- TGA – Australian SUSARs expedited
- No context, no denominator of total treated
  - Inadequate contextual info to determine:
    - If risk-benefit balance changed
    - If change requires amendment/stopping
    - If patient information requires changes
    - If monitoring trial requires changes
- Different standards of pharmacovigilance
  - Pharma sponsored
  - Investigator Initiated Studies

Nik also commented that one issue was a lack of consistent terminology and noted the following definitions had been adopted in the proposal developed from the meeting:

- SAE
  - Serious Adverse Event (usually blinded information)
- ADR
  - Adverse Drug Reaction (causality has been assigned to the treatment)
- SUSAR
  - Serious, Unexpected, Suspected Adverse Reaction
  - Causality assigned & not recorded in Investigators Brochure
  - Australian = at site in Australia
  - International = at any site outside Australia

Nik then summarised the proposal that resulted from the discussion:

- Expedited Reporting:
  - SAEs at site by Investigator
    - To Sponsor (current arrangement)
    - to HREC only if action to be taken with the study conduct on basis of SAE or if requested by HREC
    - to Institution as per State research governance arrangements
  - All SUSARs by Sponsor
    - to Investigator (as per current arrangements)
  - Australian SUSARs from Sponsor
    - to HREC via Investigator with comment
    - to TGA (as per current arrangements)
- Periodic:
  - to HREC via Investigator with comment on impact (if any) on trial conduct
    - Quarterly Listing of All SUSARs
    - Annual Listing of All Trial SAEs
  - May be more frequent if requested by HREC (eg: early Phase research)

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Nik said that the outcome from the meeting was a discussion paper, which has been circulated to other stakeholders by the attendees and the group was currently gathering feedback. The next step for the group was to consider how to implement the model, the options being looked at including whether it should be through the NHMRC under an AHMAC recommendation, and maybe separate from the National Statement, or through State Health Departments.

**The main points to come out of the Q&A session were:**

- The main priority is maintaining patient safety
- Some PIs are using the HRECs inappropriately as Data & Safety Monitoring Boards, so a mechanism was required which reduced that workload on HRECs
- Concern was expressed that this proposal was reducing HREC workload with regard to SUSARs, but that investigational staff workload in this area also needed to be addressed.
- There was a commitment to make this discussion paper and presentation is available via the PIC website under “Resources” ([www.pharmacouncil.com.au](http://www.pharmacouncil.com.au)). Further comment from stakeholders can be directed to [mitch.kirkman@novartis.com](mailto:mitch.kirkman@novartis.com).

## 6. R&D Taskforce Update and Panel Discussion

*Objective: Update stakeholders regarding progress on topics identified for follow-up at 2006 Forum and allow dialogue with forum stakeholders*

**Panel Chair: Mitch Kirkman, Chair, RDTF**

The 2006 Forum had identified four pillars of Timeliness, Quality, Value and Capacity as critical to improving or maintaining Australia's global competitiveness as a location for clinical research. To this time point, the 2007 Forum had dealt with many initiatives designed to improve Timeliness in starting clinical trials. Mitch opened the session by stating that the objective was to update stakeholders regarding progress on the initiatives proposed for follow-up by the 2006 Forum under the headings of Quality, Value and Capacity, as well as allow dialogue with forum stakeholders. The Workgroups were looking for feedback and validation from stakeholders on the directions they were taking. He introduced each of the speakers in turn and asked that questions be held for discussion at the end of the presentations.

### **6.1 Quality – Improve Research Competencies through Education**

**Marisa Petersen**  
**CEO, ARCS Australia**

Marisa began by introducing the members of the Quality Workgroup:

- Marisa Petersen and Alison van Nooten, Alphapharm (co-chairs)
- Robyn Lichter, Nucleus Network; Haryana Dhillon, Clinical Oncological Society of Australia; Anne Woolett, Andrew Love Cancer Centre
- Rachel Cameron, Tanner Menzies; Paula Mumby, I3 pharma resourcing
- Andrew McLachlan, University of Sydney
- Elizabeth Casling, DITR

Marisa then set out the Goal of the Workgroup:

- To ensure Australia continues to provide a favourable clinical trials environment to attract national and international investment by providing consistently high quality research data that is exportable globally

Marisa noted that the top issue impacting this goal – Education & Accreditation – and possible initiatives had been identified at the 2006 Forum as follows:

- Document all current education initiatives and seek framework to integrate and identify gaps
- Could draw together with education initiatives under HREC accreditation project
- Identify gatekeepers that may require evidence of accreditation/education
- Look to overseas experience
- Identify possible government support programs (DEST, DITR, State Governments)?

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which led to the Key Objective for the Workgroup:

- To develop a defined and accessible education program for clinical research staff working under the Code of Good Clinical Practice, both in institutions and industry

Marisa stressed the importance of the program being accessible both geographically and financially.

Marisa then described the Actions identified by the Workgroup to achieve this objective and progress to date:

*Action 1*

- Collect job descriptions and skill requirements by role – from industry and from research roles
- Clarify the skills gaps – as identified by members of the group, in the COSA/AHRDMA survey through a formal skills audit

*Progress*

- Quality Workgroup has completed the compilation of required skills
- Formal skills audit
  - DITR Skills Audit of the medical devices industry
  - Pharmaceutical Education Council (PEC) Skills Audit – CASR grant from DEST to undertake a Skills and Training Audit across the pharmaceutical industry and to provide and test solutions. There will be co-operation between RDTF and PEC to achieve this efficiently.
  - attendees asked to expect a survey and to complete it!

*Action 2*

- Identify the publicly available training options available via internet search (NB – limiting our work to clinical research professionals)
- Cross map the roles with skills, and skills with available training to identify gaps

*Progress*

- Quality Workgroup is writing up its informal review of training courses available nationally and will provide it to PEC together with their matrix.

Marisa said the future focus of the Workgroup included:

- Support but avoid duplication with the DEST audit
- Finalise current objectives and provide to PEC
- Focus on opportunities to extend scope of existing programs e.g. COSA Quality Assurance program
- Focus on bridge between qualification and skill competency for clinical research with the desired outcomes being:
  - a defined program for clinical research personnel including skill development, training, mentoring and assessment
  - a visible and robust Australian accreditation program

In conclusion, Marisa stated that the Workgroup's future objectives were to:

- Consider options to standardise training and development

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- Identify quantifiable measures of skills levels and associated metrics in order to provide visibility
- Explore opportunities for an Australian accreditation program
- Explore funding options to develop and support implementation of the skills development and accreditation program.

## **6.2 Value – Developing a National Clinical Trial "costing model"**

**Jenny Stephenson**

**Business Operations Director (Global Medical Affairs, Asia Pacific)**

**Bristol-Myers Squibb**

Jenny introduced the members of the Value Workgroup, described by Jenny as an "embryonic" team still looking for input across all sectors:

- Jenny Stephenson and Warren Back, Merck Sharp & Dohme (co-chairs)
- Angela Watt and Katerina Canelopoulos, Melbourne Health
- Zoe Armstrong, Merck Sharp & Dohme (previously Helen Aneudi)
- Katharine Terkuile, GSK

Jenny set out the Goal of the Workgroup:

- To ensure Australia continues to provide a favourable clinical trials environment to attract national and international investment by developing a national "costing" model to be used as the basis of all clinical trial negotiations. This "costing" model would make reference to various sources of fees and charges and provide a budgeting template/methodology for costing a clinical trial (procedures, tests, hospitalisation, ethics review, services, pharmacy, overheads)

Jenny noted that the top issue – development of a "costing" model – and possible next steps had been identified at the 2006 Forum:

- "Cost" modelling advisory committee
- National champion – suggest DITR
- National standardisation of "costing" model and clinical trial agreements
- Specified timeframe
- Recommendation to COAG (Jurisdictional Agreement)
- Funding for initiatives

Jenny commented that the landscape had changed since the 2006 Forum, perhaps emphasising an even greater need for clarity and consistency of approach:

- Overheads had increased – lack of transparency to researchers and industry
  - Are these justifiable? Who is paying?
- Total cost vs. recruitment capability
  - Non productive site – \$10-15K (Goldfarb, JCRBP)
  - Low recruiting sites costly
  - Australia falling behind traditional markets higher cost/pt recruited (personal communications)
- Greater understanding of institutional true costs

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- True costs vs. “insurance” for non-payment internally
- Variety of interdepartmental charges
- Are these competitive to similar institutes?
- Multi-centre ethics – new fee structures
  - Some unknowns
  - Some more certainty?
- Public concern over \$ incentives to volunteers (e.g. UK Phase 1)
  - Fair and reasonable – related to procedures, risks
  - Too motivational??
- Std contracts (Master Services Agreements)
  - First step

Jenny asked participants if these were issues that they faced:

- What concerns stakeholders the most?
- Are the target outcomes still valid?
- and, if so, the Workgroup was looking for representation from all sectors to ensure a robust and flexible model.

### **6.3 Capacity – Increasing Patient Involvement in Clinical Trials**

**Dr Sophie Glover-Koudounas**

**Medical Director**

**Solvay Pharmaceuticals Australia**

After outlining the context of the Capacity Workgroup within the PIC and RDTF, Sophie introduced the other member of the Workgroup: Dr Helen Ormandy, Director, Development Operations, Amgen Australia.

Sophie then set out the following:

- Goal of the Workgroup:
  - To ensure Australia continues to provide a favourable clinical trials environment to attract national and international investment by *increasing recruitment / participation in Australian trials*
- Key Objective:
  - To develop and action a defined plan to increase awareness, understanding and interest in Australian clinical trials
- Actions needed to achieve these:
  - Develop a core working group that includes key stakeholders from industry, clinical research institutions, consumer organisations, etc
  - Develop a comprehensive plan to address need to increase participation in Australia
  - Resource and action plan

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Sophie described progress to date:

- Developed work-plan defining overall goals & objectives, key actions and timelines
- Established links with Medicines Australia (MA) Health Consumer Organisations WG (HCOWG)
- Established links with other interested parties including: CHF, Leukaemia Foundation, BCNA, Stroke Foundation, Cancer Voices, NAPWA, MIMS Consumer Health

Sophie noted that, in 2005, MA HCOWG held a two day forum “*Critical Issues and Common Challenges*” involving representatives from 41 Health Consumer Organisations (HCO) and 12 Pharma companies. Common key issues that emerged related to dissatisfaction with informed consent process for clinical trial participation. Several HCO representatives, HCOWG and RDTF members held follow-up teleconferences. The outcomes have shaped the next steps for the Workgroup:

- Develop an outline of specs for communications expert to develop into “guidelines” for an easy to understand informed consent document
- Outline review by the “steering group”
- Agreed specs to be fully developed
- Review by broader stakeholder group
- Implementation

Sophie said that contact had been made with MIMS Consumer Health and several initiatives were being examined:

- Possibility of raising awareness of clinical trials to consumers through their online consumer health website: [www.mydr.com.au](http://www.mydr.com.au)
- Could provide general info about clinical trials process
- Could potentially provide info to attract consumers to specific clinical trials
- Site currently provides information, tools, links to CMIs and support groups for consumers and attracts on average 270,000 unique visitors per month

The next steps included exploring the possibility of using this site to raise awareness of clinical trials with their visitors and its use as a vehicle for recruitment

In concluding, Sophie said the Workgroup would welcome additional team members – it provided opportunities for all of us to work together.

## **6.4 R&D Taskforce Panel Discussion - Quality, Value and Capacity Initiatives**

The main points to come out of the panel session were:

### **Quality**

- There was no disagreement expressed regarding the directions being followed.
- Suitably qualified staff at clinical trials units in provincial/regional hospitals was raised as an issue in relation to barriers to recruitment. It was noted that addressing the lack of qualified staff in regional areas would have a positive effect on participation in trials and capacity.

### **Value**

- General agreement from the audience that the key issues presented under the "Value" pillar resonated with them.
- Some concern that fees for participation in Phase 1 trials are too high.

### **Capacity**

#### *Barriers*

- The complexity of the Patient Information Consent form was thought to adversely affect recruitment. Patients and their relatives are often frightened off by the descriptions of the investigational product.
- Dissatisfaction with the actual process of obtaining informed consent was seen as a barrier to recruitment.
- The proposed new CTA/CTC scheme with ANZTPA, was also seen as a barrier. The CTN scheme was seen "...to have created the industry you see before you"

#### *Incentives*

- Recruitment could be boosted by more readily including non-English speaking patients.
- Recruitment could be boosted by working in regional clinics/research units.
- Participation in trials could be increased by offering patients a fee for participation, as distinct from a contribution for out-of pocket travel costs. Is it time for the NHMRC to revise its position on this?
- Accessing the MIMS Consumer Health website could be used as a recruitment tool to increase awareness of trials.

## 7. ANZTPA Legislation Update

*Objective: Update stakeholders regarding progress towards finalisation and implementation of ANZTPA legislation in regards clinical trials*

### **7.1 Proposed Clinical Trial Regulation under the Australia New Zealand Therapeutic Products Authority (ANZTPA)**

**Dr Jonathon Rankin**  
**Experimental Drugs Section**  
**Drug Safety and Evaluation Branch**  
**Therapeutic Goods Administration (TGA)**

Jon gave a presentation on the proposed regulatory arrangements for clinical trials under ANZTPA, which were described in the Consultation Paper that had been released by the TGA since he had drafted the presentation appearing in the Forum binder given to attendees.

During the question and answer session that followed his presentation, Jon clarified issues and answered questions on the proposals raised by participants.

## 8.0 Close of Forum

**Mitch Kirkman, Chair, RDTF**

In thanking participants for their attendance and closing the Forum, Mitch Kirkman said that a clear willingness had been demonstrated by all stakeholders to continue to work together to achieve the outcomes desired, to enhance the environment for clinical research in Australia. Participants were encouraged to ensure that they actively participated in consultations on all the initiatives discussed during the Forum as these opportunities became available.

Mitch noted that a full report on the Forum, together with copies of the presentations, would be produced and posted on the PIC website under “Resources” ([www.pharmacouncil.com.au](http://www.pharmacouncil.com.au)) and on the DITR website ([www.industry.gov.au](http://www.industry.gov.au)). He also noted that the Serious Adverse Events discussion paper could be found on the PIC website under the same heading.

As a final note, Mitch encouraged anyone interested in volunteering to assist with any of the RDTF Workgroups to send an email to him – [mitch.kirkman@novartis.com](mailto:mitch.kirkman@novartis.com).