National Cancer Clinical Trials Registry Meeting

23 February 2005

A meeting to discuss the development of a national cancer clinical trials registry in Australia

Clinical Oncological Society of Australia

Roche

Funded by Roche Oncology and Haematology

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1. Foreword

At a forum entitled *Advances in Cancer Therapy and Implications for Australia* (held in Sydney September 2004) there was overall agreement from participants of the need for a National Cancer Clinical Trials Registry. Recognising that many people in the cancer field have been working to develop a clinical trials registry for many years, participants from the forum agreed that a reasonable next step would be to hold a meeting of all relevant stakeholders to progress this important initiative.

The National Cancer Clinical Trials Registry Meeting on 23rd February brought together key stakeholders – health consumer organisations, patient groups, clinicians, academics, the pharmaceutical industry (oncology), Medicines Australia, cancer councils and government – for the first time, to discuss the development of a registry.

Following the morning session, which focused on providing up-to-date information on developments in Australia and overseas, the remainder of the meeting allowed delegates to discuss and consider the parameters and requirements of a national cancer clinical trials register and expectations about what it should deliver for the cancer community.

These deliberations resulted in a number of recommendations covering a range of areas including:

- Consultation;
- Likely user groups and their needs;
- Data categories;
- Data collection and updating processes for industry and non-industry studies;
- Making the information available (access to data/support services);
- Ongoing management, sustainability and administration of the register;
- Issues specific to the cancer field relating to the inclusion of early phase (phase I) clinical trials.

On behalf of the National Cancer Clinical Trials Registry Steering Committee (Appendix I) and meeting delegates, I am pleased to share this meeting report which contains a number of specific recommendations on the development of an Australian cancer clinical trials registry. These recommendations have been forwarded to NHMRC and the Department of Health and Ageing for their consideration.

I would like to take this opportunity to especially thank members of the Steering Committee for their participation in the many preparation meetings we had to bring this initiative to fruition. Your time and commitment towards this project is appreciated. Also thanks to all the meeting participants for their valuable contributions.

I would also like to thank Roche Oncology and Haematology for their generous support in facilitating this group and convening the meeting on 23rd February. A special thank you to Leanne Jacobson and her team, and to Edelman for their ongoing Secretariat support.

Lastly, I was honored to be appointed meeting Chair for the National Cancer Clinical Trials Registry Steering Committee. It has been a pleasure working with the members of the committee in bringing this initiative to life. The commitment and support by everyone has been tremendous.

I am pleased to note that there is clear consensus on the need for a registry across all parties. It now rests with government funding bodies to take up the recommendations in this report and to fund a national clinical trials registry.

Yours sincerely

Dr Stephen Ackland
President, Clinical Oncology Society of Australia
Chair, Steering Committee – National Cancer Clinical Trials Registry

2. Executive Summary

The Clinical Oncological Society of Australia (COSA) convened this meeting to:

- Inform all key stakeholder groups of current developments towards establishing a National Cancer Clinical Trials Registry;
- Consider issues involved in the development and maintenance of a registry; and,
- Provide a consensus view to put to relevant authorities.

Fifty-six stakeholders attended the meeting (Appendix II), representing health consumer organisations, patient advocacy groups, clinicians, academics, government and the pharmaceutical industry. Delegates reached consensus on all major issues.

Overriding Recommendations

The following overriding recommendations were unanimously supported by the delegates as crucial to the development and operation of a registry.

1. The establishment of a National Cancer Clinical Trials Registry should be fully integrated with, or developed as, part of a broader National Clinical Trials Registry.
2. The development of a National Cancer Clinical Trials Registry is a key priority for all stakeholders, including:
   - Patients, carers and other health consumers;
   - Health professionals, including cancer clinical trials co-operative groups and their affiliates;
   - The pharmaceutical industry and Medicines Australia;
   - Government, and other cancer control agencies; and,
   - Ethics committees.
3. A Clinical Trials Registry is a public health facility, of potential value and importance to all Australians. As such, it should be owned by the people, and therefore managed and funded recurrently by their representative, the Federal Government.
4. The Clinical Trials Registry needs to be overseen by a broad-based, high-level Board, available to and responsive to the views of the public.
5. To ensure sustainability the funding cycle for the Clinical Trials Registry needs to be greater than five years. Ten years is considered an appropriate initial funding term once the registry is satisfactorily established.
6. Day-to-day management and maintenance of the Clinical Trials Registry should be vested in individuals / groups with an established track-record in this field. Of the options discussed by a sub-group of delegates, the National Health and Medical Research Council (NHMRC) Clinical Trials Centre was considered the preferred choice.
7. To ensure that all users' needs are met, consultation with all stakeholders is vital during the development and existence of a Clinical Trials Registry.
8. The Clinical Trials Registry needs to be comprehensive. All trials likely to inform standard clinical practice (other than exploratory trials[1]) should be included. Institutional ethics committees are the linchpin to ensure comprehensiveness.
9. In relation to exploratory trials (e.g. Phase 1, pharmacokinetics) further consultation and discussion is required to reach agreement about appropriate data elements relevant for inclusion in a registry.
   - 9.1. Cancer consumers have clearly expressed a need for Phase 1 cancer treatment trials to be included, as often these are viewed as a last chance of dealing with the disease. However industry is concerned that if mandatory Australian requirements for all Phase 1 trial details are inconsistent with international registry requirements and global industry decisions, there may be difficulties in placing Phase 1 studies in Australian sites.
   - 9.2. The debate on exploratory trials should not hold up the development of the registry.
10. The Clinical Trials Registry should include the data elements specified by the International Committee of Medical Journal Editors and the World Health Organisation (WHO) as an acceptable minimum dataset. Operational processes should be developed to minimise redundancy and the possibility of data entry errors.
11. The Clinical Trials Registry should be kept simple and precise. Links to associated sites should be included to enhance the value and utility of the registry (sponsor, investigator, consumer medicines information, general and cancer-specific information, overseas registries, dictionary of terms, etc) without burdening the registry itself with high-level detail.

Reference

[1] The phrase 'All trials likely to inform standard clinical practice (other than exploratory trials)' is intended to have the same meaning as "hypothesis-testing clinical trials", also known as "confirmatory clinical trials" as defined in the ICH Harmonised Tripartite Guideline E9 *Statistical Principles for Clinical Trials*. Stats Med 1999; 18:1905-42. Whereas exploratory trials serve to set direction (i.e. to generate hypotheses) for possible future studies, "hypothesis-testing trials" serve to examine pre-stated questions (i.e. to test hypotheses) using statistically valid plans for data analysis and provide firm evidence of safety and/or efficacy to support product claims.

12. The process of data collection needs to be simple and precise. A single on-line form is suggested. Linkage to a common national ethics committee application form is recommended.
13. Once the registry is established with a minimum dataset, COSA and its affiliates in cancer control could develop models for providing more comprehensive or detailed aspects, to streamline processes and add value to the Clinical Trials Registry for its user groups.
14. Access and availability of the register should be unrestricted. Optional information submitted voluntarily by the investigator or sponsor can be specified as confidential.
15. Tailoring dialogue and information to the needs of different stakeholders will be necessary to meet their needs. Cancer consumer organisations are willing to assist in this process.
16. The Clinical Trials Registry needs to serve New Zealand users, who have almost identical needs to Australians.

These recommendations were forwarded to the NHMRC on 1st March for consideration at a Council meeting 9-10 March (Appendix VI). At the time of writing this report, we had not heard the outcomes of the Council meeting.

3. Background

The *National Cancer Clinical Trials Registry Meeting*, supported by Roche Oncology and Haematology, brought together relevant stakeholders with an interest in the development and maintenance of a national registry for cancer clinical trials.

A desire to have a national cancer clinical trials registry has been ongoing for about 15 years. Many people have been involved in attempts to develop a cancer clinical trials registry in some form, but have always faced obstacles.

Participants at a forum, *Advances in Cancer Therapy and Implications for Australia* (2 September 2004) communicated a desire to bring all stakeholders together to progress the development of a national registry for cancer clinical trials.

In order to progress the idea, a steering committee was established to drive the agenda forward. Members of the committee included stakeholders from health consumer organisations (HCOs), clinicians and academics, representatives from the pharmaceutical industry and government (Appendix I).

A timely document, an editorial from the International Committee of Medical Journal Editors (ICMJE) 2004 – ***Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*** also lead to the development of this initiative (Appendix IV). The ICJME member journals will require as a condition of consideration for publication, registration in a public trials registry. This paper helped put discussions at the meeting in an international context.

Held on 23rd February, more than fifty people representing various stakeholders including patient advocacy groups, clinicians and academics, representatives from the pharmaceutical industry, and government – ethics committees and NHMRC, attended the meeting along with representatives from Roche Oncology and Haematology (Appendix II).

The purpose of the meeting was to:

- Provide participants with background information about clinical trial registers and inform people about developments in Australia and overseas;
- Allow stakeholders from a range of backgrounds with interests in cancer to have input into consideration of a clinical trials registry; and,
- Discuss what a register is and expectations about what it should deliver.

Divided into four sessions, the agenda (Appendix III) covered the following:

- Australian issues and perspectives;
- International issues and perspectives;
- Developing an Australian model;
- Summary and next steps.

A number of informative presentations relevant to the above areas were held during the meeting. Panel discussions were held with all presenters at the end of each session.

As one of the key aims was to seek all stakeholders' thinking and insights, the meeting was developed to be as solution-focused as possible. Thus, a number of small-group workshops were held on the following topics:

- Consultation;
- User groups and needs;
- Data categories;
- Data collection and update for industry and non industry studies;
- Inclusion of Phase 1 cancer studies;
- Making the information available;
- Establishment of the register; and,
- Ongoing management, sustainability and administration of the register.

The final session of the meeting allowed time for small group workshop chairs to present two to three key recommendations. These were debated and a full-set of recommendations developed and agreed to by all delegates (the overriding recommendations).

The meeting resulted in a consensus on number of specific aspects in relation to the development of a national cancer clinical trials registry.

This report provides:

- An overview of the presentations;
- A summary of the discussions from the sessions;
- A summary of discussions from the workshops; and,
- Recommendations from the meeting.

4. Australian Issues and Perspectives

4.1 Overview of clinical trials and perspectives, *Dr Stephen Ackland President, Clinical Oncology Society of Australia, and Chair, Steering Committee – National Cancer Clinical Trials Registry*

Dr Ackland gave an overview on the operation of cancer clinical trials in Australia, and touched on some key areas including:

– Trial initiation and sponsorship can be by international and/or national cancer trial organisations , by pharmaceutical companies, with some trials sponsored either by smaller groups of investigators or individual investigators;

– Clinical trials are governed by the ICH Code of Good Clinical Research Practice, and by the NHMRC National Statement on Ethical Conduct of Research Involving Humans ; and,

– The importance of ethics committees in the processes of approval and conduct of clinical trials.

With growing complexity and number of clinical trials, and more data being collected, it is recognised that managing trials can be burdensome, and require tremendous commitment and resources. Dr Ackland noted that clinicians want a registry as a central repository of available trials, including information about the trial design, trial sites, and whether they are open for recruitment.

While there are currently cancer trials registries (e.g. NHMRC Clinical Trials Centre and Cancer Trials NSW (AWARE)), these are poorly resourced, inadequately supported and therefore do not serve the purposes required by clinicians. A well supported nationally coordinated registry would be more likely to meet the needs of the various key stakeholders.

4.2 A patient / consumer perspective, *John Stubbs, Executive Committee, Cancer Voices*

Mr Stubbs provided delegates with a patient / consumer's perspective on the necessity for a national registry of cancer clinical trials. From his experience, he said that there is a lack of resources and information available to people with cancer and their families. He identified these as:

– Lack of information on what clinical trials are;

– Lack of details specific to a clinical trial which made it difficult for patients / consumers to adequately consider participation in a clinical trial; and,

– Lack of coordination making the available information disparate

Mr Stubbs explained that a national registry for cancer clinical trials can be an impetus for research – benefiting clinicians, researchers and industry as well as patients. He concluded that patients / consumers in the cancer community want a national registry for cancer clinical trials, emphasising that it was key that the registry is government-backed to illustrate national support with sustainable funding to ensure that the initiative continues.

4.3 The NHMRC's perspective, *Professor Alan Pettigrew, CEO, National Health Medical Research Council (NHMRC)*

Professor Pettigrew said that the vision of the NHMRC is for a single, national, independent clinical trials register for Australia that is aligned with international best practice and is publicly available nationally and internationally.

He provided an overview on how the different NHMRC committees support research in Australia and the development of a national clinical trials registry;

– Research Committee:
  - For better research and health practice;
  - To better inform practitioners, consumers, policy;
  - To better inform research grants and awards processes;
  - To meet the International Committee of Medical Journal Editors (ICJME) requirements;

– Australian Health Ethics Committee
  - To ensure details and results of a trial are available; and,
  - To ensure honest reporting.

Professor Pettigrew reported progress on the development of NHMRC's proposal to provide an enabling grant scheme for a national clinical trials register for all disease areas. A steering group comprising members of the Research Committee and the Australian Health Ethics Committee has been formed to ensure that the register meets the requirements of the NHMRC which include the following:

– Governance
  - High-level board – broadly based;

– Ownership – independent
  - Joint NHMRC / TGA initiative, but located and managed at Cancer Trials Center;
  - Legal arrangements;

– Mandatory / voluntary?
  - Via ethics;

– Minimum data set
    - ICJME requirements, international developments;
– A Unique Identifier will be required – on an international basis – to avoid redundancy;
– Funding – an enabling grant of five years, with a review at three years;
– Technical issues; and,
– Sustainability – beyond the enabling phase, and need for a long term location / governance of the registry.

Also underway are discussions with the New Zealand Health Research Organisation on the possibility of merging clinical trials information, and ongoing dialogue with other agencies at national and international levels.

He commended the initiative by the various stakeholders in cancer, and said that having a registry is valuable to all health areas; while it cannot be restricted only to cancer, the issues peculiar to cancer trials and patient needs can be considered specifically.

4.4 Pharmaceutical industry view on a national clinical trials registry, *Ms Deborah Monk, Medicines Australia*

A meeting held by Medicines Australia on 17th February 2005 brought together representatives from oncology companies to discuss their views on the establishment of a National Cancer Clinical Trial Registry. Ms Monk presented those views.

The overall principle is that the industry operates in an international arena and the forces impacting the industry in Australia are not just local, so the establishment of a registry needs to be considered within an international framework

Highlights from her presentation include:

– While there are concerns primarily about managing the data – input and maintenance – a simple straightforward mechanism linked to current processes is needed for maximum efficiency;
– Confidentiality in relation to commercial interests in a clinical trial is not an impassable barrier, but the industry needs to be respected and consulted when developing the NCTR; and,
– There is strong support for the joint position statement on the disclosure of clinical trial information via clinical trial registries and databases by the European Federation of Pharmaceutical Manufacturers and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers and Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Ms Monk concluded by saying that a national clinical trials register is inevitable, and maintained that Medicines Australia wants to be a part of the solution – working with everyone to ensure that participation in clinical trials is enhanced.

Key issues raised

Following the above presentations, the following key issues were discussed during the panel session:

– Core data set to be as inclusive as possible;
– Incorporating relevant information, and availability of clinical trials;
– Development of the Australian registry according to international best practice standards;
– Registration of clinical trials and which trials to include;
– Other information outside of the trial protocol that may need to be included (e.g. lay descriptions of the trial, patient information, etc).

5. International Issues and Perspectives

5.1 World Health Organisation (WHO) initiative: progress and prospects, *Professor Alan Pettigrew, CEO, National Health Medical Research Council (NHMRC)*

Prof Pettigrew shared with delegates a presentation, *WHO International Clinical Trial Registry Platform from A. Metin Gulmezoglu, Project Coordinator – Department of Reproductive Health and Research, WHO*. WHO has been addressing the issue of clinical trials registries over the last several months.

The presentation highlighted the WHO's view of the necessity for the registration of clinical trials, citing it as a fulfillment of ethical obligation to participants and the public, while addressing the problem of publication bias. Other advantages include:

– Contribution to the development of unbiased systematic reviews;

– Advancement of science – quick disclosure of results, increase in effectiveness of research funding, and increased participation by patients, doctors and researchers; and,

– Increasing transparency of information about trials – reducing over-reporting and ambiguity.

Other components of the presentation included a brief section on the history of trials registration and WHO's role in global health systems research – participating in the various stakeholder meetings and discussions around the world.

Professor Pettigrew also shared key points from the WHO International Clinical Registry Stakeholders' meeting, October 2004 at Rockefeller Foundation, New York. Stakeholders stated that there was a need for a global approach to trials registration. Key points from the meeting included:

– The need for an unambiguous identification of trials;

– Consensus on which trials, data, timing and disclosure of results;

– A one-stop search portal that is publicly available;

– A system that is simple, effective and efficient; and,

– And where appropriate, capacity building.

Stakeholders at that meeting also indicated that a formal process be established. Whilst it will be a broad collaborative process, appropriate governance will be necessary. The meeting was mindful of the International Committee of Medical Journal Editors July 2005 deadline which requires – as a condition of consideration for publication – registration of clinical trials in a public registry. Whilst existing structures will be leveraged, the need for any new structures will progressively be identified.

Several WHO committees are working on aspects of standardisation and coordination of registries, including standards and principles, technical implementation, and startup funding. Professor Simes (NHMRC Clinical Trials Centre) participates in the technical advisory group, while Professor Pettigrew, NHMRC sits on the international advisory board

Professor Pettigrew also highlighted that Australia's involvement in the WHO initiative would allow for a sharing of Australia's views at an international level.

5.2 The US model: what we can learn, *Ms Mary McCabe, Director, Cancer Survivorship Program, Memorial Sloan-Kettering Cancer Center, New York*

Ms McCabe was formerly the Nursing Director at the Lombardi Cancer Center, Washington, DC, and between 1988 and 2003, held a number of positions at the National Cancer Institute (NCI). She gave an overview of the NCI's Physician Data Query (PDQ(r)) – a long-running cancer information database. As background on the necessity for clinical trials registries in the US, the AMA have published data indicating that <50% of clinical trials are published, >1/3 of all randomised trials are not indexed in Medline, and by 2000, only half of all study abstracts had reached full publication. She said that although there is now a growing interest in registries, they have long been discussed in the oncology community. Developing a useful clinical trials registry requires overcoming many hurdles, particularly with regard to the type of data / information to be collected, the completeness of the data base and the ability to keep the information up to date.

She indicated that voluntary data submission is generally a hindrance, as it leads to incompleteness and lack of transparency. Ms McCabe highlighted that patient advocates are major drivers in promoting and expanding the PDQ database.

Other factors promoting the maintenance and enhancement of the PDQ database are the desire to enhance patient care through evidence-based practice; incentives to share data; and increasing movement to monitor the literature for improved health outcomes; and a convergence of political pressure.

To illustrate the existence of registries, Ms McCabe reported a list of legislatively mandated registries. These include the NCI's PDQ – which is under the National Cancer Act of 1971; AIDS info and the National Library of Medicine's ClinicalTrials.gov.

Ms McCabe informed that a federal review of US clinical trials web sites (2002) has assessed the role of web sites in fostering informed consent, as well as provided oversight of IRBs (ethics committees), contributed to setting of voluntary standards and independent review.

Ms McCabe described the various components of the PDQ including:

- Cancer information summaries
    - That help patients and families understand and know the status of the clinical trial;
- Cancer genetics services directory; and,
- Directories of persons and organisations involved in cancer care
    - Dictionary of cancer terms
    - Clinical terminology – NCI is happy to share this with Australia's proposed national registry.

PDQ currently has 2200 open trials in its database and >14000 trials closed to patient accrual. 50-75 new protocols are added per month.

Her suggestions for the development of Australia's national registry include:

- Having a unique identifier – that will assist in bridging the gap between trials and protocol summaries;
- Having summaries available – identifying what is truly valuable to patients / consumers and what is affordable to add-on to a registry;
- While the aim is for having information available, accurate and up to date information is the only type that is valuable;
- Remember who the information is for – what is the reading level of people accessing the information, how understandable the information is, and the quality of the information;
- The necessity to know the specifics required by the different stakeholders; and,
- Having sustainability for management – bearing in mind scope to evolve / progress the registry.

Ms McCabe concluded by informing that the NCI is happy to collaborate with Australia on its national register, and will be interested to align a list of studies.

5.3 Key issues raised

Following the above presentations, the following key issues were discussed during the panel session:

- The cost of resources (e.g. staff, set-up) when establishing a registry;
- The process in timely accurate and reliable data entry and maintenance, particularly for multi-centre studies – checking for accuracies and status of clinical trials;
- Whether to progress the development from an existing registry, or to start building a new registry;
- Methods for seamless input / updates of data between registries – example; Australia and overseas, or between databases elsewhere eg. PDQ and clinicaltrials.gov;
- The thinking and strategy for considering Phase 1 trials;
- The possibility of having a minimum core data set for Phase 1 trials, that satisfies the needs of stakeholders while protecting the possible commercial interests;
- Whether to include clinical trials for alternative therapies;
- Ensuring that the data is complete and that all appropriate trials are registered;
- Consensus on the most important user group(s); and,
- Consensus on the primary user.

6. Developing an Australian Model

6.1 Initial planning: what the model might look like, *Professor John Simes, Director of National Health Medical Research Council (NHMRC) and Ms Marie Malica, Project Manager, Cancer Trials NSW*

Professor Simes provided an overview of the structure for what a model might look like, while Ms Malica shared her experience from The Cancer Council NSW's cancer trials project and the council's upcoming project AWARE (Accessible Website And REgister of Australian Cancer Trials).

Professor Simes shared that the aims of the NHMRC's national clinical trials register are to:

– Develop and maintain a comprehensive, prospective, national register of clinical trials: including trials of any healthcare interventions (example: lifestyle, drugs, surgery and devices);

– Make information on ongoing trials readily accessible to investigators, patients and funding groups;

– Increase participation in ongoing clinical trials by better informing healthcare practitioners and patients and their families;

– Provide a reliable and unbiased source of information for systematic reviews, prospective meta-analyses and evidence-based guidelines;

– To provide a national repository of all approved cancer clinical trials occurring in Australia;

– To allow access by cancer health professionals and potential consumers as well as cancer control bodies to this knowledge; and,

– To facilitate a national assessment of cancer clinical research activities occurring in Australia.

He also highlighted requirements to consider for the development of a registry. These were primarily criteria for:

– Registering clinical trials;

– Collecting data set;

– Updating and keeping the registry comprehensive; and,

– Ensuring confidentiality of sensitive information.

Ms Malica shared that the aim of AWARE is to improve participation and access to cancer trials by increasing the awareness of consumers, clinicians and researchers. The need for the registry to be user-friendly and informative was illustrated with screen shots from the internet pages of the Council's cancer trials project – which had pages of different information that a person with cancer (and their friends and family) will find useful. Examples of web-pages about cancer trials, *10 things to know about clinical trials, cancer trials NSW, list of trials and patient stories.*

6.2 Shaping the model: building a framework for future development

Meeting delegates divided into different discussion groups. Delegates chose the discussion group in which they were keen to participate. Each discussion group, led by a chairperson, then met to discuss key questions on the identified topic.

The groups and summaries of their discussion are below:

6.2.1 User groups and their needs, *Chairperson: Ms Sally Crossing, Co-Chair, Cancer Voices NSW, Breast Cancer Action Group*

Discussion Questions:

– Who are the key groups that need to be able to use the register? For what broad purposes?

– What are the particular needs of each group in relation to the quality and type of information on the register and access to this information?

Outcomes:

– User groups were identified as:
  - Patients (current and future);
  - Carers;
  - Clinicians;
  - Researchers;
  - Industry;
  - Information helplines;
  - Policy makers/strategists (Government and Government departments);
  - Ethics committees;
  - Consumer advocates; and,
  - Guideline developers / practice evaluators.

– Broad purposes included:
  - Information about treatment options;
  - Assessment tool of current research activities to formulate national cancer research plan;
  - Provision of a contact to obtain additional information;
  - Increase recruitment (institutions, clinicians, consumers, patients, industry);
  - Increase participation (institutions, clinicians, consumers, patients, industry); and,
  - Provide hope for patients and carers.

– Particular needs identified:
    - An accessible and easy to navigate consumer and clinical / technical version;
    - Link from consumer version to the Cancer Information Service in each state and territory to make it easier for consumers to get additional information. Should also include a 'Dictionary of Terms' similar to the National Cancer Institute (NCI);
    - Crucial that information is updated but need to be realistic as to how often this can be done – annually was suggested;
    - Participating sites and contact details required;
    - Eligibility criteria; and,
    - Clear presentation.

Considerations:

– Costs for two versions of the registry (patient and health professional);

– Access to privacy / confidential information – security levels within the registry; and,

– Information needs to be made available in a format specific to the needs of both lay people and healthcare professionals.

6.2.2 Data categories, *Chairperson: Dr Ian Olver, Chairman, Medical Oncology Group of Australia*

Discussion Questions:

– Which studies should be included and which should be not?

– What core data items are needed? What optional data items might there be?

– Are there some data items that your group would specifically exclude from the registry? At what points? Why?

Outcomes:

– Minimum data set for the registry to be in-line with World Health Organisation (WHO) criteria and medical journal editors; and,

– Functional and easily accessible links to more information are required – particularly for it to be useful to clinicians.

Considerations:

– The amount of detail that should be included in the register; and,

– Decision on whether to include Phase 1 studies is needed (see Overriding Recommendations).

6.2.3 Data collection and update for industry and non-industry studies, *Chairperson: Dr Martin Stockler, Director, Cancer Trials NSW*

Discussion Questions:

– Who will be responsible for submitting the initial data?

– At what points should data be submitted and updated?

– How will information on the data base be kept current? By whom?

– How will compliance with the requirements of the data base be assured?

– What role might ethics committees play?

Outcomes:

– The sponsor / study chair should be responsible for submitting the initial data;

– Data should be submitted at commencement of study, and updated frequently
    - The sponsor / study chair will be responsible for updates;
    - Submission of data to be done online, with consistency and quality check before the information goes 'live';

– Compliance should be managed by submission to Health Research Ethics Committees that a trial has been registered before it can be activated; and,

– Ethics Committee and TGA to ensure that the trial has been registered
    - To also make available a single form for submission.

6.2.4 Making the information available, *Chairperson: Ms Jane Cruickshank, Cancer Voices NSW, Cancer Advocacy Network*

Discussion Questions:

– Who should have access to the information?

– Should there be restricted access to any data? To whom? Why? How?

– How will the various groups you have identified gain access to the information?

– Will there need to be any support services?

Outcomes:

– The group reached consensus that the following people should have access to the registry (with certain caveats): consumers, clinicians, researchers, policy makers, industry, ethics committees;

– Consensus was reached that the register should be a web-based interface with a phone support structure to allow access to those who are not online. It was agreed that it is the sponsors' responsibility to support clinical trials with a helpline to offer support to interested consumers particularly for Phase 1 and early Phase 2 trials; and,

– The group agreed that a certain support structure was appropriate to ensure that consumers, in particular, were armed with contextual information which explained how participation in a clinical trial differed from standard hospital treatment and what a patient's overall survival options / benefits might be as a result of participation in a clinical trial.

Considerations:

– Forms for 'informed consent' – for patients with questions relating to potential involvement in a clinical trial; and,

– Training / modules / programs for patient advocacy groups to assist them to answer questions and respond appropriately to consumer / patient requests – can be obtained via the NCI.

6.2.5 Linking the Australian register with other registers and information sources

Note: This discussion group did not proceed, as meeting delegates had higher priorities for the other topics to be discussed.

6.2.6 Establishment of the register, *Chairperson: Ms Davina Ghersi, Director, Systematic Review Register, NHMRC Clinical Trials Centre*

Discussion Questions:

– What steps should be in the project plan?

– Which organisations might take carriage of developments?

– How and at what points will the key groups of stakeholders be engaged?

– What are the options for how the developmental phase might be funded? Your preferred option?

Outcomes:

– Phase 1 of the project plan would be the development of a timeline with clear information about the minimal data requirements for the registry. Phase 2 will focus on developing the registry further, including a dictionary and the AWARE site;

– The NHMRC should continue to take carriage of developments; and,

– The Government should be the sole option for funding – from experience without government support, the registry will not be successful. The Federal Health Minister, Tony Abbott should be briefed as soon as possible.

Considerations:

– Resources and funding to make the registry a success;

– Ongoing communication with stakeholders; and,

– Efficient research methods.

6.2.7 Ongoing management and administration of the register, *Chairperson: Dr Steve Ackland (Chair), President, Clinical Oncology Society of Australia*

Discussion Questions:

– What are the options of who should manage and administer the register? Your preferred option?

– What are some options for ongoing funding? Your preferred option?

– How will key stakeholder groups contribute to developments?

– What will be the performance measurements?

Outcomes:

– An Australian organisation with the experience, facility and staff to manage and administer the registry – example: NHMRC CTC;

– Registry to be recognised as part of core healthcare by the government;

– Funding for 10 years is required – a five-year grant is insufficient to progress the development of the registry;

– Stakeholder contributions are: formal regular review, surveys and representation on sub-committees; and,

– Performance measurements identified: data quality, satisfaction of users and trial participation rates.

Considerations:

– Ongoing funding (beyond the preferred option of 10 years) to sustain the management (and further development) of the registry.

7. Conclusion

This report illustrates the commitment, of the Committee in particular and all stakeholders in cancer care in general, towards the development of the registry, as well as highlighting the unanimous support of the delegates (from the meeting). There was clear agreement that the concept of a National Cancer Clinical Trials Registry is a high priority.

As a next step, the Committee through COSA proposes a targeted media campaign to communicate to key medical media, and targeted health consumer organisations. The media outreach will:

– Communicate the initiative to the broader cancer community; and,

– Share the initiative and the recommendations to support for a national cancer clinical trial registry, and potentially progress development for it.

It is hoped that the delegates including the Steering Committee for the National Cancer Clinical Trials Registry (and stakeholders from the broader cancer community) endeavour to maintain the dialogue and interest on this important initiative, and to remain in close contact with the NHMRC and the broader cancer community.

Appendix I – Steering Committee Members

Dr Steve Ackland (meeting Chair),
President, Clinical Oncology Society of Australia

Mrs Margaret McJannett,
Executive Officer, Clinical Oncology Society of Australia

Ms Marie Malica,
Project Manager, Cancer Trials NSW

Dr Martin Stockler,
Director, Cancer Trials NSW

Ms Rada Kusic,
Clinical Trials Manager, Cancer Institute NSW

Professor Jim Bishop,
Cancer Institute NSW

Professor John Simes,
Director, National Health and Medical Research Council – Clinical Trials Centre

Professor John Zalcberg,
Chair, Australasian Gastro Intestinal Trials Group

Professor David Ball,
Chair, Trans-Tasman Radiation Oncology Group

Professor Ian Olver,
Chairman, Medical Oncology Group of Australia

Ms Jane Cruickshank,
Cancer Voices NSW, Cancer Advocacy Network

Mr John Stubbs,
Executive Committee, Leukaemia Foundation NSW, Cancer Voices NSW

Ms Davina Ghersi,
Director, Systematic Review Register, National Health and Medical Research Council – Clinical Trials Centre

Dr Mark Hertzberg,
President, Haematology Society of Australia

Prof. Max Wolf,
Chairman Australian Lung and Lymphoma Group

Ms Sally Crossing,
Co-Chair, Cancer Voices NSW, Breast Cancer Action Group

Dr Fran Boyle,
Medical Oncologist, Royal Prince Alfred Hospital

Professor Alan Pettigrew,
CEO, National Health Medical Research Council (NHMRC)

Ms Brigid Waite,
Group Medical Manager, Roche Products

Dr Mark Amies,
Associate Medical Director, Roche Products

Ms Leanne Jacobson,
Oncology / Haematology Franchise Manager, Roche Products

Dr David Kingston,
Medical Director, Roche Products

Ms Amie Wakefield,
Account Director, Edelman

Ms Kris Ashpole,
Associate Director, Edelman

Appendix II – Delegates

Dr Steve Ackland,
President, Clinical Oncology Society of Australia

Mrs Margaret McJannett,
Executive Officer, Clinical Oncology Society of Australia

Ms Marie Malica,
Project Manager, Cancer Trials NSW

Dr Martin Stockler,
Director, Cancer Trials NSW

Ms Rada Kusic,
Clinical Trials Manager, Cancer Institute NSW

Ms Mary McCabe,
Director of Survivorship Program, Memorial Sloan-Kettering Cancer Centre, USA

Prof. John Simes,
Director, National Health and Medical Research Council – Clinical Trials Centre

Professor Ian Olver,
Chairman, Medical Oncology Group of Australia

Professor Alan Coates,
Chief Executive Officer, The Cancer Council Australia

Ms Haryana Dhillon,
Medical Psychology Research Unit, University of Sydney

Dr Jonathon Rankin,
Head and Medical Advisor of Experimental Drugs Section, Therapeutic Goods Administration

Professor Robyn Ward,
Senior Staff Specialist, Department of Medical Oncology, St Vincent's Hospital

Ms Deborah Monk,
Director of Scientific and Technology Affairs, Medicines Australia

Professor Mark Elwood,
Director, National Cancer Control Initiative

Ms Jane Cruickshank,
Executive Committee, Cancer Voices NSW

Mr John Stubbs,
The Leukaemia Foundation NSW, Executive Committee, Cancer Voices NSW

Dr Anna Williamson,
National Research Sevices and Advocacy Director, The Leukaemia Foundation of Australia

Ms Davina Ghersi,
Director, Systematic Review Register, National Health and Medical Research Council Clinical Trials Centre

Associate Professor Mark Hertzberg,
President, Haematology Society of Australia and New Zealand

Ms Ann Porcino,
Director and Principal Consultant, RPR Consulting

Ms Sally Crossing,
Chair, Cancer Voices NSW, Breast Cancer Action Group

Dr John Seymour,
Department of Haematology and Medical Oncology, Peter MacCallum Cancer Centre

Dr Chris Arthur,
Head of Haematology Department, Royal North Shore Hospital

Ms Greta Riley,
Project Manager, Cancer Trials, New Zealand

Dr Jane Glatz,
Business Development Director, Research Australia

Dr Devinder Gill,
Chair, Cancer Collaborative Group, Princess Alexandra Hospital

Ms Ainsley Martlew,
Senior Policy Analyst, Health Ethics Branch, Department of Health, NSW Health

Dr Alison Evans,
Program Manager, National Breast Cancer Centre

Ms Kathy Hall,
Research Manager, Trans Tasman Radiation Oncology Group

Mrs Susan Fitzpatrick,
Executive Officer, Clinical Research, The Cancer Council Victoria

Professor Alan Pettigrew,
Chief Executive Officer, National Health and Medical Research Council

Mr Peter Herak,
Project Officer, National Health and Medical Research Council

Mr David Clayton,
Area Control Operations Director, Abbott

Dr Dominic Barnes,
Medical Affairs Director, Janssen-Cilag

Dr Carlo Maccarrone,
Head of Clinical Research, GlaxoSmithKline

Dr Colin Yeoman,
Senior Medical Advisor, Schering Pty Ltd

Ms Jacqui Wade,
Clinical Research Manager, Pfizer Australia

Dr John Patava,
Clinical Trials Manager, Schering Pty Ltd

Ms Kristina Cabala,
Clinical Research Director, Pfizer Australia

Ms Anne Woollett,
Chair, Clinical Oncology Society of Australia, Data Managers Group

Ms Jenny Ebsary,
Head of Clinical Research Unit, Sanofi Aventis

Ms Kaylene O'Shea,
Director of Scientific Affairs, Amgen Australia

Mr Mitch Kirkman,
Clinical Research Manager, Novartis Pharmaceuticals

Dr Jeffrey Hassall,
Medical Director, Bayer Australia

Ms Eleanor Whitehead,
Clinical Projects Manager, Oncology, AstraZeneca

Ms Pamela Jenkin,
Clinical Projects Team Manager, Oncology, Eli Lilly Australia

Ms Kirsten O'Doherty,
Director, Prescription Medicines, Roche Products

Dr Mark Amies,
Associate Medical Director, Roche Products

Ms Zoe Silverstone,
Medical Writer, Roche Products

Ms Leanne Jacobson,
Oncology/Haematology Franchise Manager, Roche Products

Ms Rita Corrente,
Public Relations Manager, Roche Products

Ms Jude Love,
Marketing Manager Prescription Medicines, Roche Products

Ms Amie Wakefield,
Account Director, Edelman Health (secretariat)

Ms Kris Ashpole,
Associate Director, Edelman Health (secretariat)

Ms Michele Ng,
Account Manager, Edelman Health (secretariat)

Ms IngerLise Jensen,
Account Executive, Edelman Health (secretariat)

Appendix III – Agenda

Purpose of the meeting

– To provide participants with background information about clinical trial registers and inform people about developments in Australia and overseas.

– To allow stakeholders from a range of backgrounds with interests in cancer to have input into consideration of a clinical trials registry

– To discuss what a register is and expectations about what it should deliver.

Time	Agenda Item and process	Speaker
8.30	**Registration and coffee**	
9.00 – 9.30	**Session 1: Welcome and overview of the meeting**	
9.00 (10 min)	**1.1 The purpose of the meeting**	Dr Stephen Ackland, President Clinical Oncological Society of Australia (COSA)
9.10 (20 min)	**1.2 The meeting process**	Ms Ann Porcino Facilitator RPR Consulting
9.30 – 11.00	**Session 2: Australian issues and perspectives**	
9.30 (10 min)	**2.1 Overview of clinical trials in Australia**	Dr Stephen Ackland
9.40 (10 min)	**2.2 A consumer perspective**	Mr John Stubbs, Cancer Voices
9.50 (30 min)	**2.3 The NHMRC's perspective**	Professor Alan Pettigrew, CEO, National Health Medical Research Council (NHMRC)
10.20 (10 min)	**2.4 A perspective from the pharmaceutical industry**	Ms Deborah Monk, Medicines Australia
10.30 (30 min)	**2.5 Questions and discussion**	
11.00 – 11.15	**Morning tea**	
11.15 – 12.40	**Session 3: International issues and perspectives**	
11.15 (15 min)	**3.1 WHO initiative: progress and prospects**	Professor Alan Pettigrew
11.30 (40 min)	**3.2 The US model: what we can learn**	Ms Mary McCabe, Director, Cancer Survivorship Program, Memorial Sloan-Kettering Cancer Center, New York
12.10 (30 min)	**3.3 Questions and discussion**	
12.40 – 1.30	**Lunch**	

1.30 –	**Session 4: Developing an Australian Model**	
1.30 (30 min)	**4.1 Initial planning: what the model might look like**	Professor John Simes, Director National Health Medical Research Council, Clinical Trials Centre (NHMRC), Marie Malica, Research Strategy Unit, The Cancer Council NSW
2.00 (15 min)	**4.2 Questions and discussion**	
2.15 (1 hour)	**4.3 Shaping the model: building a framework for future development** *Some of the proposed workshop topics for the day are:* • User groups and their needs • Data categories • Data collection and update for industry and non industry studies • Making the information available • Linking the Australian register with other registers and information sources • Establishment of the register • Ongoing management and administration of the register *Please note: further groups/may be decided upon on the day to meet individual needs of participants small groups:*	Workshop discussion
3.15 – 3.30 (15 min)	**Afternoon tea**	
3.30 (1 hour)	**4.4 Plenary discussion**	
4.30 – 5.00	**Session 5: Summary and next steps**	
4.30 (10 min)	**5.1 Summary of key aspects of plenary discussion**	Ms Ann Porcino
4.40 (20 min)	**5.2 Conclusions and next steps**	Dr Stephen Ackland

Appendix IV – Editorial

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors

Altruism and trust lie at the heart of research on human subjects. Altruistic individuals volunteer for research because they trust that their participation will contribute to improved health for others and that researchers will minimize risks to participants. In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly. Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor's product.

Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalence of two approaches to treatment (noninferiority trials). Researchers (and journals) typically are less excited about trials that show that a new treatment is inferior to standard treatment (negative trials) and even less interested in trials that are neither clearly positive nor clearly negative, since inconclusive trials will not in themselves change practice. Irrespective of their scientific interest, trial results that place financial interests at risk are particularly likely to remain unpublished and hidden from public view. The interests of the sponsor or authors notwithstanding, anyone should be able to learn of any trial's existence and its important characteristics.

The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. Rather than a single trial, it is usually a body of evidence, consisting of many studies, that changes medical practice. When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines or decide on insurance-coverage policy. If all trials are registered in a public repository at their inception, every trial's existence is part of the public record and the many stakeholders in clinical research can explore the full range of clinical evidence. We are far from this ideal at present, since trial registration is largely voluntary, registry data sets and public access to them vary, and registries contain only a small proportion of trials. In this editorial, published simultaneously in all member journals, the International Committee of Medical Journal Editors (ICMJE) proposes comprehensive trials registration as a solution to the problem of selective awareness and announces that all 11 ICMJE member journals will adopt a trials-registration policy to promote this goal.

The ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment prior to this date, the ICMJE member journals will require registration by September 13, 2005, before considering the trial for publication. We speak only for ourselves, but we encourage editors of other biomedical journals to adopt similar policies. For this purpose, the ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (for example, phase I trials), would be exempt.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the following information: a unique identifying number, a statement of the intervention (or interventions) and comparison (or comparisons) studied, a statement of the study hypothesis, definitions of the primary and secondary outcome measures, eligibility criteria, key trial dates (registration date, anticipated or actual start date, anticipated or actual date of last follow-up, planned or actual date of closure to data entry, and date trial data considered complete), target number of subjects, funding source, and contact information for the principal investigator. To our knowledge, at present, only www.clinicaltrials.gov, sponsored by the United States National Library of Medicine, meets these requirements; there may be other registries, now or in the future, that meet all these requirements.

Registration is only part of the means to an end; that end is full transparency with respect to performance and reporting of clinical trials. Research sponsors may argue that public registration of clinical trials will result in unnecessary bureaucratic delays and destroy their competitive edge by allowing competitors full access to their research plans. We argue that enhanced public confidence in the research enterprise will compensate for the costs of full disclosure. Patients who volunteer to participate in clinical trials deserve to know that their contribution to improving human health will be available to inform health care decisions. The knowledge made possible by their collective altruism must be accessible to everyone. Required trial registration will advance this goal.

Catherine De Angelis, MD, MPH
Editor-in-Chief, *Journal of the American Medical Association*

Jeffrey M. Drazen, MD
Editor-in-Chief, *The New England Journal of Medicine*

Professor Frank A. Frizelle, MBChB, MMedSc, FRACS
Editor, *The New Zealand Medical Journal*

Charlotte Haug, MD, PhD, MSc
Editor-in-Chief, *Norwegian Medical Journal*

John Hoey, MD
Editor, *Canadian Medical Association Journal*

Richard Horton, FRCP
Editor, *The Lancet*

Sheldon Kotzin, MLS
Executive Editor, MEDLINE
National Library of Medicine

Christine Laine, MD, MPH
Senior Deputy Editor, *Annals of Internal Medicine*

Ana Marusic, MD, PhD
Editor, *Croatian Medical Journal*

A. John P.M. Overbeke, MD, PhD
Executive Editor, *Nederlands Tijdschrift voor Geneeskunde*
(Dutch Journal of Medicine)

Torben V. Schroeder, MD, DMSc
Editor, *Journal of the Danish Medical Association*

Harold C. Sox, MD
Editor, *Annals of Internal Medicine*

Martin B. Van Der Weyden, MD
Editor, *The Medical Journal of Australia*

Source: International Committee of Medical Journal Editors (ICJME) 2004

www.icjme.org/clin_trial.pdf

Appendix V – Presentations and How to Access

Overview of clinical trials and perspectives, *Dr Stephen Ackland President, Clinical Oncology Society of Australia, and Chair, Steering Committee – National Cancer Clinical Trials Registry*

A patient / consumer perspective, *John Stubbs, Executive Committee, Cancer Voices*

The NHMRC's perspective, Professor Alan Pettigrew, CEO, National Health Medical Research Council (NHMRC)

Pharmaceutical industry view on a national clinical trials registry, *Ms Deborah Monk, Medicines Australia*

World Health Organisation (WHO) initiative: progress and prospects *– WHO International Clinical Trial Registry Platform, A. Metin Gulmezoglu, Project Coordinator – Department of Reproductive Health and Research, WHO; presented by Professor Alan Pettigrew CEO, National Health Medical Research Council (NHMRC)*

The US model: what we can learn, *Ms Mary McCabe, Director, Cancer Survivorship Program, Memorial Sloan-Kettering Cancer Center, New York*

Developing An Australian Model – Initial planning: what the model might look like, *Professor John Simes, Director of National Health Medical Research Council (NHMRC) and Ms Marie Malica, Project Manager, Cancer Trials NSW*

For full versions of the above presentations, please contact Leanne Jacobson at Roche on (02) 9454 9000.

Appendix VI – Letter and Overriding Recommendations

Clinical Oncological Society of Australia

1st March, 2005

Professor Alan Pettigrew
CEO
National Health and Medical Research Council
Level 5, 20 Allara Street
Canberra, ACT 2601

Dear Professor Pettigrew

Re: National Cancer Clinical Trials Registry Meeting, Wednesday 23rd February 2005

Thank you for attending this meeting and for presenting the position and current work of the National Health and Medical Research Council and the World Health Organisation. We regret your unavailability during the more interactive part of the workshop.

The meeting was the culmination of a significant amount of work on the concept of a National Clinical Trials Registry by a number of stakeholders.

Following the morning session which focused on providing up-to-date information on developments in Australia and overseas, the remainder of the meeting allowed delegates to discuss and consider the parameters and requirements of a national cancer clinical trials register and expectations about what it should deliver for the cancer community.

These deliberations resulted in key recommendations covering a number of areas including:

– Consultation
– Likely user groups and their needs
– Data categories
– Data collection and updating processes for industry and non-industry studies
– Making the information available (access to data/support services)
– Ongoing management, sustainability and administration of the register
– Issues relating to the inclusion of early phase (phase I) clinical trials, for cancer in particular

On behalf of the Clinical Trials Registry Steering Committee and meeting delegates, I am pleased to present to you with the attached recommendations for your consideration and that of the National Health and Medical Research Council meeting on 9-10 March. These primary recommendations have been strongly agreed to by all delegates representing health consumer organisations, patient groups, clinicians, academics, the pharmaceutical industry (oncology), cancer councils and government.

The Cancer Council Australia

(Affiliated with The Cancer Council Australia)

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GPO Box 4708, Sydney NSW 2001
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We are producing a more detailed meeting report, which will include recommendations and information on specific operational aspects of the registry as related to cancer trials. We will be forwarding this report to you in due course. Meanwhile, if you have any comments or questions in relation to the recommendations please do not hesitate to contact me on 0408 492 868 or 02 49 211 146.

I look forward to discussing specifics of the development of the national cancer clinical trials registry further with you (of course in context of the plans for a national registry for all disease areas) and to progressing this important initiative as quickly as possible.

Yours sincerely

Dr Stephen Ackland
President, Clinical Oncology Society of Australia
Chair, Steering Committee – National Cancer Clinical Trials Registry

cc: Ian Kemp, A/g Director, Cancer Section, Department of Health and Aging
Peter Herak, Project Officer, National Health and Medical Research Council

encl: National Cancer Clinical Trials Registry Meeting: Key Recommendations
National Cancer Clinical Trials Registry Meeting: Delegate List

Key Recommendations

Background

The Clinical Oncological Society of Australia (COSA) convened this meeting to:

Inform all key stakeholder groups of current developments towards establishing a National Cancer Clinical Trials Registry;

Consider issues involved in the development and maintenance of a registry; and

Provide a consensus view to put to relevant authorities.

Fifty-six stakeholders attended the meeting, representing health consumer organisations,patient advocacy groups, clinicians, academics, government and the pharmaceutical industry – a list of attendees is attached. Delegates reached consensus on all major issues.

Recommendations

The following broad recommendations were unanimously supported by the delegates as crucial to the development and operation of a registry.

1. The establishment of a National Cancer Clinical Trials Registry should be fully integrated with or developed as part of a broader National Clinical Trials Registry.
2. The development of a National Cancer Clinical Trials Registry is a key priority for all stakeholders, including:
   - Patients, carers and other health consumers
   - Health professionals, including cancer clinical trials cooperative groups and their affiliates
   - The pharmaceutical industry and Medicines Australia
   - Government, and other cancer control agencies
   - Ethics committees
3. A Clinical Trials Registry is a public health facility, of potential value and importance to all Australians. As such, it should be owned by the people, and therefore managed and funded recurrently by their representative, the Federal Government.
4. The Clinical Trials Registry needs to be overseen by a broad-based, high-level Board,available to and responsive to the views of the public.
5. To ensure sustainability the funding cycle for the Clinical Trials Registry needs to be greater than five years. Ten years is considered an appropriate initial funding term once the registry is satisfactorily established.
6. Day-to-day management and maintenance of the Clinical Trials Registry should be vested in individuals / groups with an established track record in this field. Of the options discussed by a sub-group of delegates, the NHMRC Clinical Trials Centre was considered the preferred choice.
7. To ensure that all users' needs are met, consultation with all stakeholders is vital during the development phase of a Clinical Trials Registry and continuously throughout its existence.
8. The Clinical Trials Registry needs to be comprehensive. All trials likely to inform standard clinical practice (other than exploratory trials1) should be included. Institutional ethics committees are the linchpin to ensure comprehensiveness.
9. In relation to exploratory trials (e.g. Phase 1, pharmacokinetics) further consultation and discussion is required to reach agreement about appropriate data elements relevant for inclusion in a registry.
   - 9.1. Cancer consumers have clearly expressed a need for Phase 1 cancer treatment trials to be included, as often these are viewed as a last chance of dealing with the disease. However industry is concerned that if mandatory Australian requirements for all Phase 1 trial details are inconsistent with international registry requirements and global industry decisions, there may be difficulties in placing Phase 1 studies in Australian sites.
   - 9.2. The debate on exploratory trials should not hold up the development of the registry.

10. The Clinical Trials Registry should include the data elements specified by the International Committee of Medical Journal Editors and the World Health Organisation (WHO) as an acceptable minimum dataset. Operational processes should be developed to minimise redundancy and the possibility of data entry errors.
11. The Clinical Trials Registry should be kept simple and precise. Links to associated sites should be included to enhance the value and utility of the registry (sponsor, investigator, consumer medicines information, general and cancer-specific information,overseas registries, dictionary of terms, etc) without burdening the registry itself with high-level detail.
12. The process of data collection needs to be simple and precise. A single online form is suggested. Linkage to a common national ethics committee application form is recommended.
13. Once the registry is established with a minimum dataset, COSA and its affiliates in cancer control could develop models for providing more comprehensive or detailed aspects, to streamline processes and add value to the Clinical Trials Registry for its user groups.
14. Access and availability of the register should be unrestricted. Optional information submitted voluntarily by the investigator or sponsor can be specified as confidential.
15. Tailoring dialogue and information to the needs of different stakeholders will be necessary to meet their needs. Cancer consumer organisations are willing to assist in this process.
16. The Clinical Trials Registry needs to serve New Zealand users, who have almost identical needs to Australians.

Reference

[1] The phrase 'All trials likely to inform standard clinical practice (other than exploratorytrials)' is intended to have the same meaning as "hypothesis-testing clinical trials", also known as "confirmatory clinical trials" as defined in the ICH Harmonised Tripartite Guideline E9 *Statistical principles for Clinical Trials*. Stats Med 1999; 18:1905-42. Whereas exploratory trials serve to set direction (i.e. to generate hypotheses) for possible future studies, "hypothesis-testing trials" serve to examine pre-stated questions (i.e. to test hypotheses) using statistically valid plans for data analysis and provide firm evidence of safety and/or efficacy to support product claims.

Notes

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Notes

For a full version of the presentations, please contact Leanne Jacobson at Roche on (02) 9454 9000

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