‘National Reforms: Harmonisation of single ethics review - HoMER Update”

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Presentation

• Context of National Change
• Context of Change in Queensland Health
• Pharmaceutical Industry Working Group
National Context

- Australian Health Ministers Advisory Council (AHMAC) Report – *HoMER 2006 and subsequent support made in 2009*

  *This committed all the States to a programme of reform for research ethics and governance*

- Re-issue of National Statement 2007
- Issue of Code of Responsible Conduct 2007

*Key message*

*Separation of Ethical and Scientific review from Research Governance AND Minimise duplication of ethical and scientific review for multi-centre research*
Context of Change in Queensland

• Smart State Council Report November 2007
  Medical Research: Queensland’s Future
  Health and Wealth: Solving Tomorrow’s
  Health Problems Today

• R&D Strategy 2009
  Research for a healthier future: 2020 Health
  and Medical Research and Development
  Strategy 2009
Initiative 3: Improved systems for ethics, research governance and research administration

- Queensland Health Research Management Policy and Implementation Standards
- Information System – AU RED – shared with NSW and Victoria – includes the On-Line form and Site Specific Assessment
- Standard Operating Procedures for HREC administration and Research Governance
- Standard Clinical Trials Agreement for industry, CROs and Collaborative Groups and appointment of single panel firm
Initiative 3: Improved systems for ethics, research governance and research administration

- Networks – HREC Chairs and Administrators, Research Governance Officers, Clinical Research Coordinators.
- Researcher support materials
- Central Coordination Service for Multicentre Research
- Standard fee schedule for commercially sponsored research
- Coordinating Principal Investigator Guidelines
Pharmaceutical Industry Working Group (PWIG)

In response to the shift in the clinical trials market the Commonwealth Departments of Industry, Tourism and Resources and Health and Ageing - Pharmaceutical Industry Working Group (PWIG) have established. The aim of the ‘Group’ is to focus on developing a roadmap for keeping global clinical trials in Australia.

- Coordinate, nationwide approach to clinical trials
- Develop performance measures
- National patient referral networks; and
- Better ways to approve, establish and conduct clinical trials.
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