

**PHARMACEUTICALS INDUSTRY COUNCIL**

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# A Model for AE Reporting and Review for Australia

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1 March 2007

Pharmaceuticals Industry Council R&D Taskforce (PIC RDTF) 2007 Forum:  
An Update on a National Approach to Clinical Trials  
Organised in association with ARCS Australia



**Australian Government**  
**Department of Industry**  
**Tourism and Resources**

# Background

- Centralised HREC review
  - NSW, Vic, Qld
- AHMAC Working Group
  - A national streamlined ethical review system
  - Stop redundant reviews
  - Decrease HREC workloads
- Ongoing issue
  - SAE Management by HRECs

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# PIC RDTF Hosted Forum

- Objective
  - Develop a more rational process for HREC review of SAEs
- Date
  - Canberra, 06 Sep 06
- Stakeholders attending (from AHMAC WG):
  - Commonwealth - TGA, NHMRC AHEC
  - HRECs/Scientific committees - NSW SSAS, PMCI
  - States Health – NSW, WA
  - Researchers – NSW Cancer Institute, CTA
  - Industry – Novartis, BI, MSD, GSK, Quintiles

# Issues

- Volume of SUSARs/SAEs to HRECs
- No uniformity with Sponsors in level of AE info supplied
  - some all SAEs, some only unexpected

# Issues

- Responsibilities in regulations vs guidelines unclear
  - National Statement
    - “that may effect the conduct of trial”
    - All SAEs
  - Regulations global and local
    - IND re AEs to IRBs
    - TGA – Australian SUSARs expedited

# Issues

- 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

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# Issues

- Different standards of pharmacovigilance
  - Pharma sponsored
  - Investigator Initiated Studies



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# Terminology

- SAE
  - Serious Adverse Event (blinded)
- ADR
  - Adverse Drug Reaction (causality)
- SUSAR
  - Serious, Unexpected, Suspected Adverse Reaction
  - Causality & not in Investigators Brochure
  - Australian = at site in Australia
  - International = at any site outside Australia

# Proposal

- SAEs at Sites under HREC approval
- To HREC
  - if investigator feels will impact on the study and action is planned as a result or
  - if requested by HREC
- To Institution
  - as per State research governance arrangements

# Proposal

- Annual Summary of all SAEs  
(Australian and International in the trial)

- To HREC (via Investigator)
  - Comment re action or if no action planned
  - Could be requested more frequently by HREC

# Proposal

- SUSARs occurring in Australia

- To HREC (via Investigator)
  - comment by investigator if action or no action planned
- To TGA (via Sponsor)
  - as per current requirements

# Proposal

- All SUSARS  
(Australian and International)
  - To Investigators
    - Expedited (No change)
  - To HREC (via Investigator)
    - Listing at least quarterly with comment
    - Timing to allow EU reports to be utilised

# Proposal Summary

- Expedited:
    - SAEs at site
      - to HREC if action to be taken
    - To Institution via State research governance arrangements
  - All SUSARs
    - to Investigator
  - Australian SUSARs
    - to HREC via Investigator with comment
- 
- Periodic:
    - Quarterly Listing of All SUSARs
    - Annual Listing of Trial SAEs
      - Both to HREC via Investigator with comment

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# Outcome – Discussion Paper

- Circulated to other stakeholders (by attendees)
- Currently gathering feedback
- Consider how best implement:
  - NHMRC under AHMAC recommendation
    - separate to National Statement?
  - State Health Departments