



Association of Australian Medical Research Institutes

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AAMRI submission to the proposed clinical trial regulatory arrangements under the Australia New Zealand Therapeutic Products Authority (ANZTPA)

The Association of Australian Medical Research Institutes (AAMRI) welcomes the opportunity to comment on the proposed clinical trial regulatory arrangements under the Australia New Zealand Therapeutic Products Authority (ANZTPA).

AAMRI represents 36 independent medical research institutes across Australia. The AAMRI Institutes are independent not-for-profit organisations, closely affiliated to hospitals and universities. They carry out much of Australia's most distinguished health and medical research and are major partners in the commercialisation of Australia's biomedical discoveries.

Australia currently has a competitive advantage in the clinical trials area due to our excellent safety record and reasonable timeframe for assessment of clinical trials.

It is in the interests of the continued success of the clinical trials industry that there is a robust evaluation and assessment of clinical trials, however, it is also important that any new system does not have unintended consequences. The proposed changes would have serious implications for the clinical trials industry. The loss of a CTN-like scheme for First in Human and early phase clinical research would result in Australia losing its international competitiveness in early phase research.

This would have flow on effects such as:

- Biotech Clinical development would be driven off-shore with the loss of Phase I units in Australia and biotech companies would face longer and more costly development timelines. In these circumstances, many would need to licence earlier with less attractive terms. This would lead to ongoing leakage of Australian research to international markets with very little return to the Australian economy and to the institutions such as AAMRI Institutes involved in the discovery of new treatments.
- International pharmaceutical companies will stop placing Phase I studies in Australia /New Zealand – their key driver is the current efficient evaluation of studies under the CTN system which has subject safety as the primary objective of the review. International studies account for 70-80% of commercial Phase I studies in Australia.
- Loss of international Phase I studies would have two effects on the specialist phase I units –
 - The units would not be economically viable and would close down
 - The units would lose access to world leading study design, a learning experience that is able to be transferred for the benefit of the local biotech industry

- Australian patients would thus lose early access to novel, life saving medical developments. There would be little incentive for international companies to place studies here without the fast approval timelines.
- Australia is facing increased competition from India and China in attracting clinical studies and if there is a loss of Phase I studies to Australia this will result in a decrease in the number of Phase II and Phase III studies.

AAMRI strongly supports the proposed alternative model prepared by EPCRA (Early Phase Clinical Research Australia) – see submission attached.

AAMRI believes that the EPCRA alternative model provides a very high level of participant protection through experienced and competent ethics committees for the review of the trials, in combination with experienced and well equipped staffed sites.

- AAMRI and EPCRA believe that participant safety in early phase studies is best protected by conducting these studies at specialist sites after review by expert committees, close to the site of conduct. EPCRA proposes a self-certification system for First-in-Human (FTIH) clinical trial sites. Subsequent to certification as having FTIH competence, these centres could nominate the CTC approach for FTIH and other Phase I trials. Upon nominating the CTC approach, the certified centres would require review by a Phase 1/FTIH AHEC endorsed ethics committee. ANZTPA would be encouraged to audit the FTIH facilities to ensure compliance under the self-certification system.
 - EPCRA and AAMRI propose that Ethics and Scientific committees experienced in phase I and FTIH study review be self-certified and endorsed by AHEC as competent to conduct these evaluations based on a review of a complete Investigator Brochure (IB) and protocol which directly address the criteria outlined in the draft EMEA (European Agency for the Evaluation of Medicinal Products) guidance for potential high-risk medicinal products released in March for consultation. Certified committees would have in place mechanisms to seek independent expert review appropriate to the investigational product and protocol. An outline of the self-certification requirements for FTIH/ Phase I committees is appended to this document.
 - Adopting the certified centre/ committee approach would allow ANZTPA resources to focus CTA review on studies where the relevant committee and / or site did not have the necessary experience in the conduct of FTIH studies. This would have the effect of directing ANZTPA resources towards protecting participants at greatest risk.
 - For those Phase I studies that do follow a CTA path, EPCRA and AAMRI recommends the adoption of the MHRA timelines in order for Australia to remain internationally competitive. These timelines are published on the MHRA website as being an average of 14 calendar days and a maximum of 21 calendar days for Phase I studies.
 - Implementation of the system as described in the consultation paper would lead to delays in Phase I and FTIH studies (45 working day review and all FTIH through CTA system) and have a significant detrimental impact on the Australian pharma and biotech industry.
- Putting at risk \$50 million p.a. of Phase I studies in Australia
 - Driving Australian biotechs off-shore for Phase I

- Increasing costs for Australian biotechs by 30 – 50% for Phase I and increasing timelines by 3 – 6 months
 - Reducing Australian participation in Phase II & III studies as follow-on from early phase work
 - Reducing early access for Australians to new medicines
 - Loss of Australian expertise in drug development to overseas sites
- There is no evidence that central regulatory review via CTA like process provides greater protection than the proven safety achieved via experienced Human Research Ethics Committee (HREC) review
- CTC 'approval' process is an unnecessary delay and increases bureaucracy over a successful, notification system. The power for the ANZTPA to stop a study under a notification system should be addressed through an amendment to the Director's orders stating that all trials conducted under a CTC could be stopped by the agency for cause.

AAMRI strongly supports a safe and efficient clinical trials industry in Australia and is keen to see this grow and continue to flourish. In 2005 AAMRI Institutes had over 300 major discoveries already being used in the health system or under development and it is important that there is every opportunity for commercialisation of medical research in Australia.

AAMRI would appreciate any further opportunities to discuss the changes to the clinical trials regulatory arrangements and would be happy to supply any other information required.



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