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WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



# 22<sup>nd</sup> Asian Harmonization Working Party Annual Meeting



4-8 December, 2017 | New Delhi





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# Clinical Trial Environment Australia

Catherine Bourgeois  
Abbott  
Director Field Clinical Affairs  
ANZ, India, Korea, SE Asia





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# AGENDA

- ❑ The Importance of Clinical Trials in Australia
- ❑ What Factors are Important to Attract Trials to Australia
- ❑ New Australian Initiatives to Improve the Clinical Trial Environment







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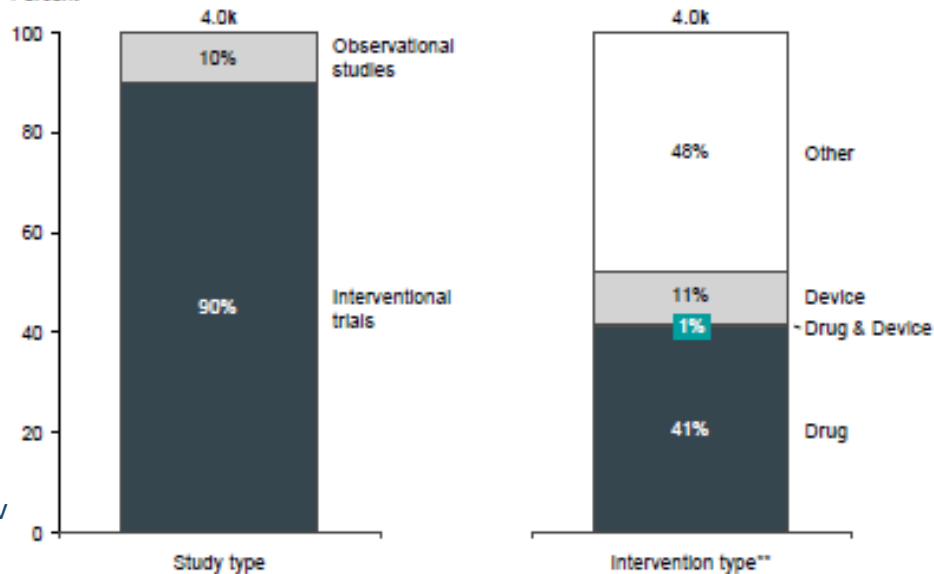


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# Clinical Trial Activity in Australia

**Clinical trials started in Australia\***  
(CY2013,14,15)  
Percent



Source: ANZCTR & ClinicalTrials.gov





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## Clinical Trial Activity Growth 2010 - 2015

	Drug	Device	Drug & Device	Other	Total
<b>Growth (p.a.2010 – 15)</b>	2.7%	12.6%	13.4%	5%	4.7%



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## Clinical Trial Activity Growth 2010 - 2015

- ❑ Global average for Medical Device trials ~ 2%
- ❑ Australian average for Medical Device trials ~ 13%
- ❑ Growth in Australia is significantly above world average





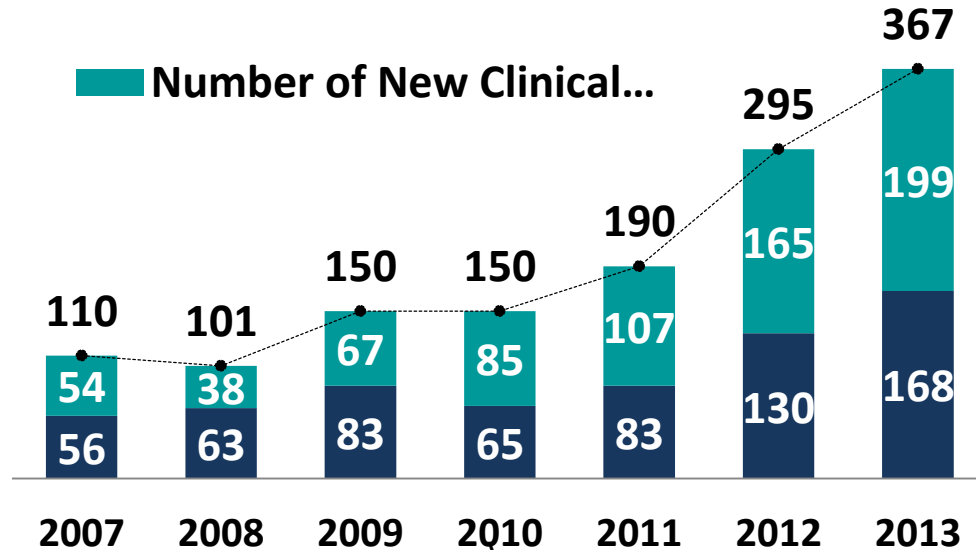
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# Number of New Clinical Trials – Medical Devices – TGA Data



Source: Therapeutic Goods Administration, Half-Yearly Performance Reports, Clinical Trials (Medical Devices)





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# Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research







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# AIMS

1. Understand what value Australia derives from involvement in industry funded clinical research as judged by investigators and study staff
2. Clarify “spill over” benefits
  - Direct
  - Indirect





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# Survey Demographics

## Role & Experience of Survey Participants

Investigators: 88% (n=165)

Study Coordinators: 8% (n=15)

Other: 4% (n=7)

Years working in research: 16.5yrs (Av.)





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# Summary – Direct Benefits

## Funding

- 69% of trials and clinical research projects are industry funded

## Resources

- 47% of site's research workforce is funded by industry
  - 16% of Investigator roles
  - 78% of Study Coordinator/other roles





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# Summary – Indirect Benefits

## Patient

- Facilitates early **patient access** to new treatments
- Improves the **standard of care**







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# Summary – Indirect Benefits

## Investigator

- Supports **academic research**
- Provides **technical experience** and **global recognition** to Australian researchers





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## Summary – Indirect Benefits

### Department of Health:

- Enhances uptake of **new evidence** into clinical practice
- Helps **retain researchers** in the Australian health care system





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# Summary – Indirect Benefits

## Government:

- Creates and maintains **high-skilled jobs**
- Brings in foreign **investment**





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# The Clinical Research Industry in Australia Provides

- ❑ ~1,360 new clinical trials commence in Australia annually
- ❑ Contribute \$1.1billion AUD to the national economy
- ❑ Funds for research infrastructure & academic projects
- ❑ Over 6,900 jobs supporting clinical trial activities

Source: Clinical Trials in Australia: The economic profile and competitive advantage of the sector. MTP Connect June 2017







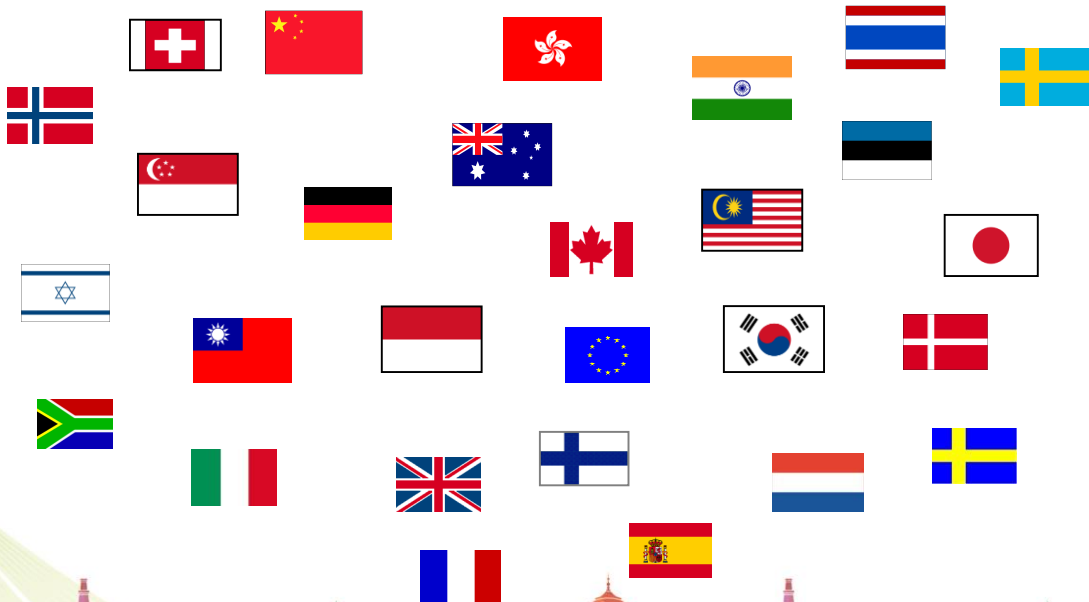
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# Global Competitiveness for Clinical Trials





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## Country Selection for Clinical Trials

<b>Quality</b>	ICH Good Clinical Practice, Medical Expertise
<b>Recruitment Capacity</b>	Reliably recruit patients committed Size of patient contribution
<b>Speed</b>	Rapid start up Patient recruitment
<b>Cost (Value)</b>	Cost (per patient) Efficiency (pts/site, pts/CRA)



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# Global Competitiveness for Clinical Trials





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Australian Government

**CLINICALLY COMPETITIVE:**  
BOOSTING THE BUSINESS OF  
CLINICAL TRIALS IN AUSTRALIA  
CLINICAL TRIALS ACTION GROUP REPORT







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## CTAG Key Recommendations

- Streamline ethics and governance processes
- Examine the costs of conducting clinical trials in Australia
- Integrate eHealth initiatives into clinical trials
- Develop a web portal to improve patient access to clinical trials





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## McKeon Review Recommendations

- Implement clinical trial reforms as an urgent national priority
- Acceleration of CTAG recommendations
- Enhance the existing consumer portal
- Establish 8–10 national ethics committees to replace the proliferation of local committees
- Create a national clinical trials office to drive reforms.

Australian Government Department of Health and Ageing (2013), *Strategic Review of Health and Medical Research: Summary Report*.  
Commonwealth of Australia





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# Global Competitiveness for Clinical Trials

## Key Enablers:

- CTN scheme.
- National Mutual Acceptance Scheme.
- Short ethics review timeframes for private sites.
- Experienced researchers and site study coordinators.





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# Global Competitiveness for Clinical Trials

## Key Enablers:

- Established referral networks and national patient databases.
- Nationally approved contract template
- R&D Tax Incentive







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# Global Competitiveness for Clinical Trials

## Key Barriers:

- No national single ethics approval process – public/private
- Risk associated with single ethics submission.
- Lack of clarity, consistency, transparency and timeliness of governance approvals.
- Inability for sponsor organisation to communicate directly with IRB





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## Quality

### Development of VET Accredited Course

- Hospital administrators and researchers who oversee clinical trials or submit applications

### E-Learning Modules

- The clinical trials environment
- Ethical aspects of clinical trials
- Research governance related to clinical trials





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# Quality

## ❑ Safety Monitoring

- Revised Position Statement: *Monitoring and Reporting of Safety for Clinical Trials*
- In preparation:
  - Data Safety Monitoring Boards and Alternative Safety Review Bodies
  - Reporting of Serious Breaches for the Clinical Trial Protocol for Trials Involving Therapeutic Goods







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# Recruitment Capacity

## ❑ AustralianClinicalTrials.gov.au

- Access to trial information and to register participant's interest

<https://www.australianclinicaltrials.gov.au/>





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# AustralianClinicalTrials.gov.au



National Health and Medical Research Council  
Department of Industry, Innovation and Science

AustralianClinicalTrials

Have an account? Click [here](#) to login

Home

For consumers

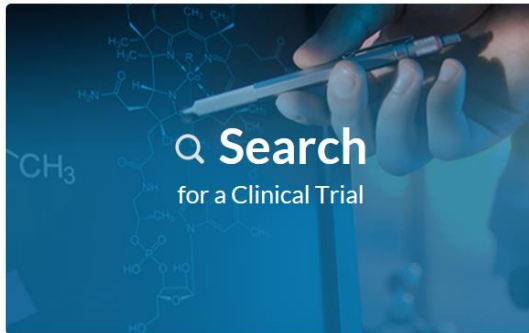
For health care providers

For industry and sponsors

For researchers

eLearning Modules

Further resources



Follow Australian Clinical Trials



Log in to Subscribe for new Clinical Trials alerts



## Real stories



[David Briggs, Enthusiastic Trial Participant](#)

I am in awe of the trials teams and how competent and motivated they are. How could I not want to help them in their quest to improve cancer therapies for people like me?

[View all stories](#)

## Latest Information

[Real story videos of participants and researchers now published!](#)

[You can now subscribe and receive alerts of new trials](#)

[Australia celebrates International Clinical Trials Day!](#)

[View the NHMRC webinar on the Human Research Ethics Application \(HREA\) @](#)

## Australian Government Clinical Trials Initiatives

Updated 1 September 2016

An overview of current activities to improve the clinical trials environment



[What is a clinical trial](#)



[Why be part of a clinical trial](#)



[How to be part of a clinical trial](#)



[Consumer guide to clinical trials](#)



[eLearning Modules](#)



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# Speed

## □ Streamlining Research Governance

- Reduce start up times and inconsistencies
- Developed a *Good Practice Process* for site assessment and site authorisation
- Completed a pilot study at 16 sites





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## Speed

### New Human Research Ethics Application form

- Released Q4/16

### Streamlining Ethics Review

- Establishing national scientific committees to provide advice on medical device and complex genetic research
- Develop a tool for HREC to identify relevant National & State laws when reviewing CTs in multiple jurisdictions





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## Speed

### □ Clinical Trial Jurisdictional Working Group (CTJWG)

- Identify barriers and enablers to streamlining multijurisdictional clinical trials
- Senior official from Commonwealth, State & Territory Health Depts + NHMRC
- Framework for collecting metrics and performance data





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## Cost

- ❑ **Independent Hospital Pricing Authority (IHPA)** has conducted two reviews on costs of clinical trials
  - Two reports released - provided standard costing tables (2014 and 2016)





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## Summary

- The Australian Government has recognised the importance of clinical trials
- Many initiatives are underway both at the federal and state level to improve the environment
- The number of Medical Device clinical trials in Australia are increasing above the global average





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## Conclusion

- Reducing the administrative burden
- Facilitating patient access to clinical trials
- Encouraging hospitals to engage in research
- Have contributed to the growth of clinical trials in Australia







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Thank You

