

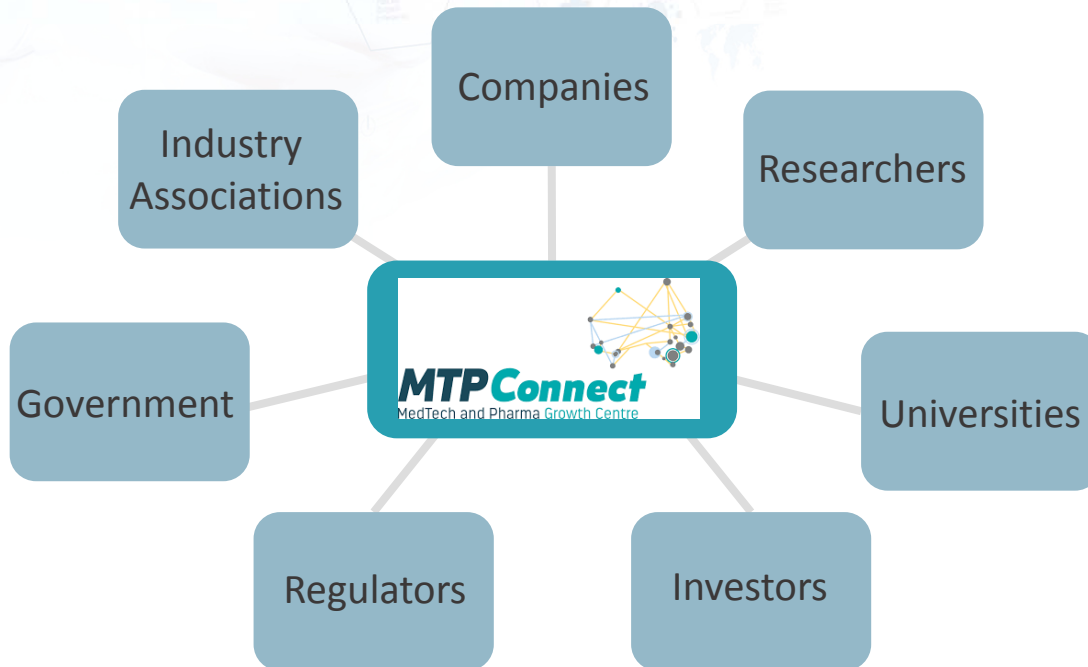


MTP *Connect*

MedTech and Pharma Growth Centre

The Economic Benefit of Clinical Trials in Australia - AusMedtech
Sue MacLeman – CEO, MTPConnect

MTPConnect's goal is to accelerate growth of Australia's MTP sector



MTPConnect

- Established by the Australian Federal Government
- Goal is to accelerate the rate of growth of the medical technologies, biotechnologies and pharmaceuticals sector to achieve greater commercialisation and establish Australia as an Asia-Pacific hub for MTP companies

OUTCOMES



Regulatory reform



Improved access to global supply chains and international markets

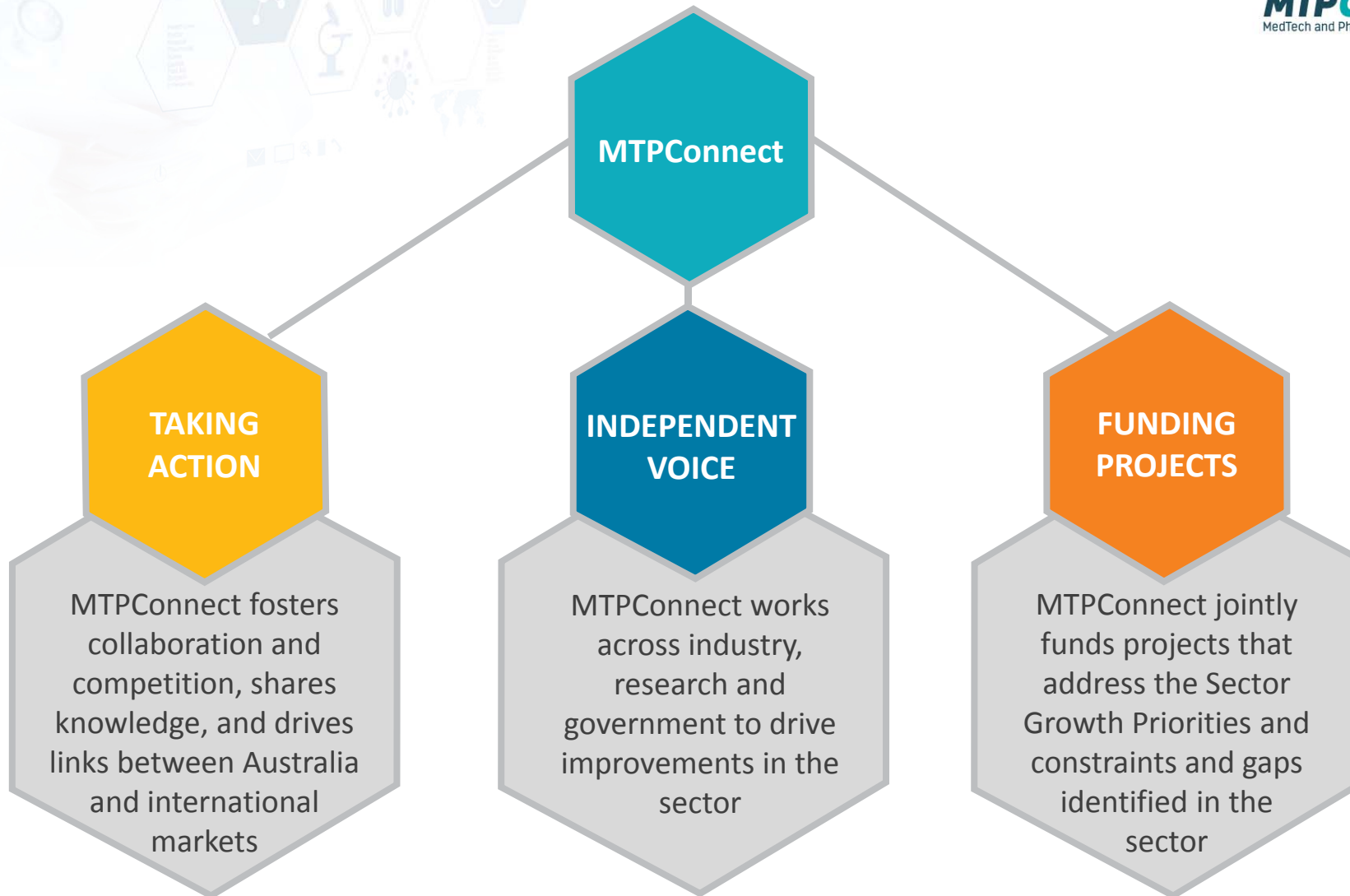


Improved engagement between research and business



Improved management and workforce skills

MTPConnect's role



The clinical trial sector in Australia is a significant contributor



Up to
1,360

TRIALS STARTED in
2015 (ANZCTR)



\$1.1b

in **GROSS**
EXPENDITURE
on all ongoing
trials in 2015



c.6,900

JOBS SUPPORTED,
largely tertiary
qualified

Why Australia is attractive for clinical trials



Sophisticated and scale research environment

- World class infrastructure
- Leading scientists, physicians and HCPs
- High standards of care
- Widespread use of high-end drugs, devices, diagnostics
- First-class clinical trials infrastructure and skills



Robust and rapid regulatory environment

- Internationally recognised system for new drugs and devices
- Rapid clinical trials approval system - CTN/CTX
- Effective intellectual property (IP) rights protection system



Strong ties to Asian Markets

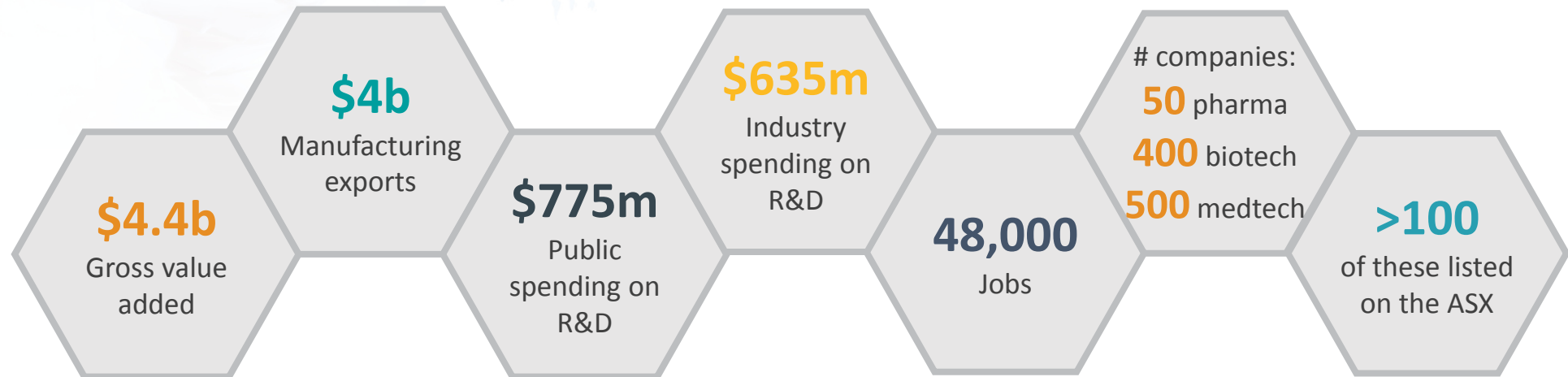
- Geographically close to Asia, similar time zones
- Strong ties with the Asia- Pacific region, supported by Free Trade Agreements (FTAs)
- Ethically diverse population and seasonal differences



Cost competitive

- Globally cost competitive
- Competitive R&D tax incentive scheme that rewards investment in Australian R&D
- Rapid set up times (which reduces cost)

The medtech, biotech and pharmaceutical sector in Australia is diverse



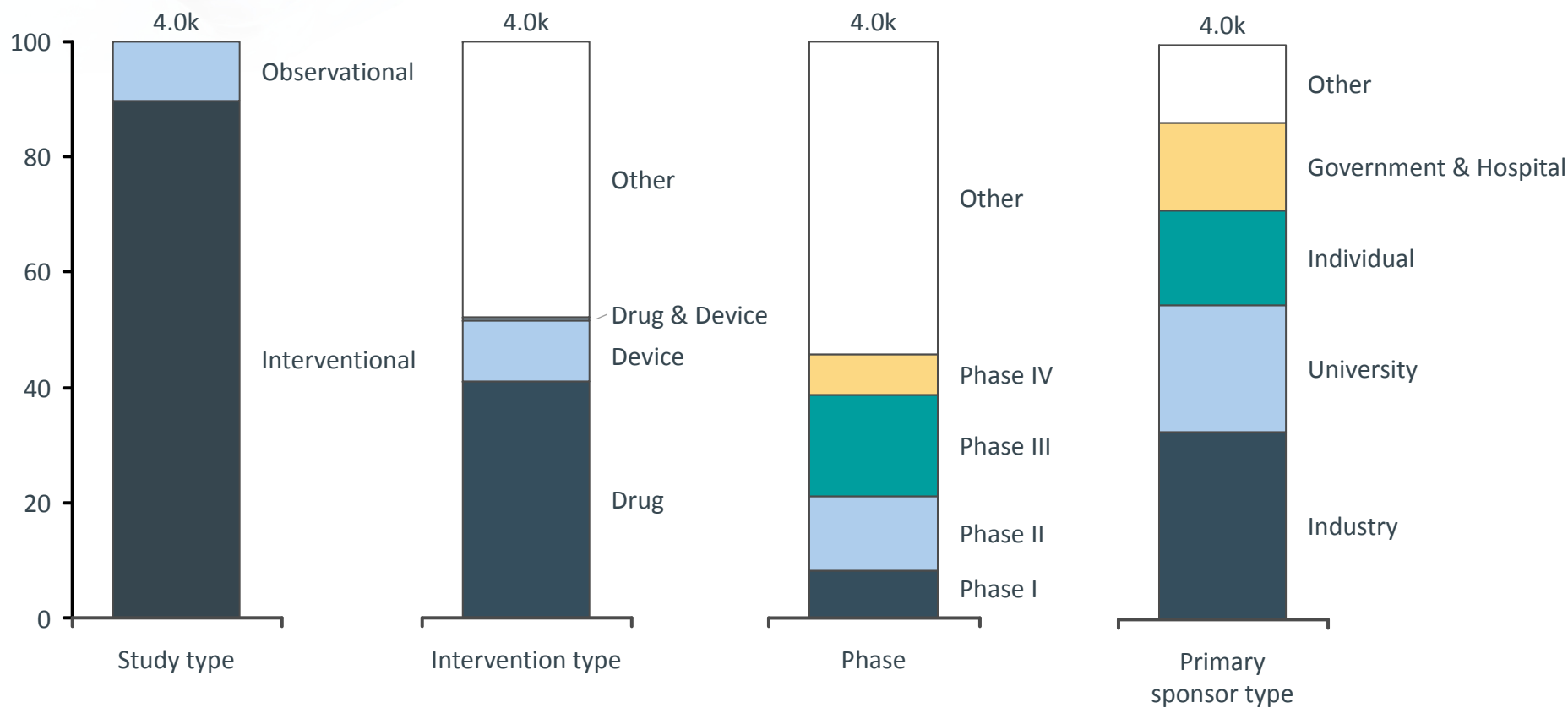
- 50 Clinical Trial Networks
- 40 Universities
- 30 Contract Research Organisations
- Plus thriving industry of clinical trial support services including Biobanks, Phase I units, central laboratories, industry bodies, NFPs, Government Departments

The majority of trials in Australia are interventional trials sponsored by a range of sector participants



Clinical trials started in Australia (ANZCTR)
(CY2013,14,15)

Percent

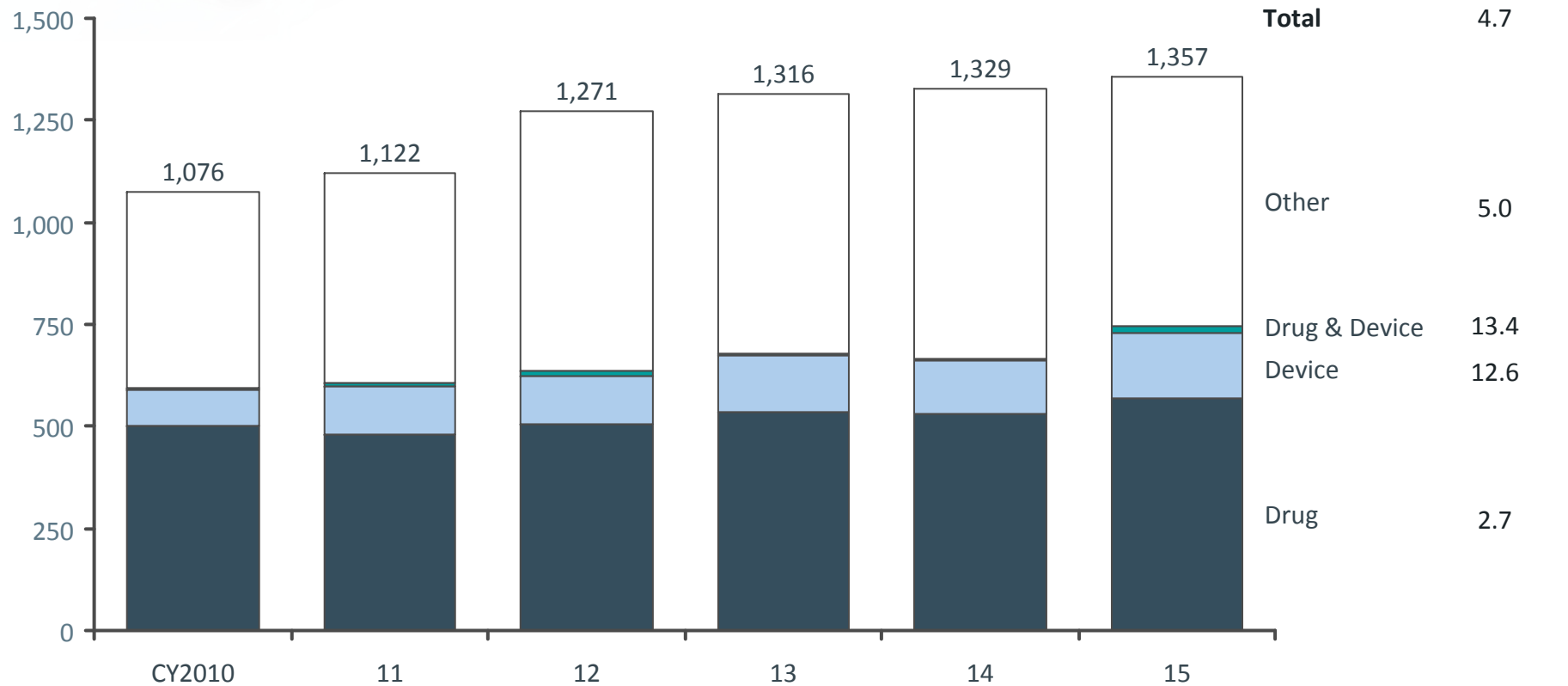


Drug and device trials make up the majority of studies and have experienced strong growth



Clinical trials started in Australia, by intervention type (ANZCTR)
(CY2010-15)

Number of trials started

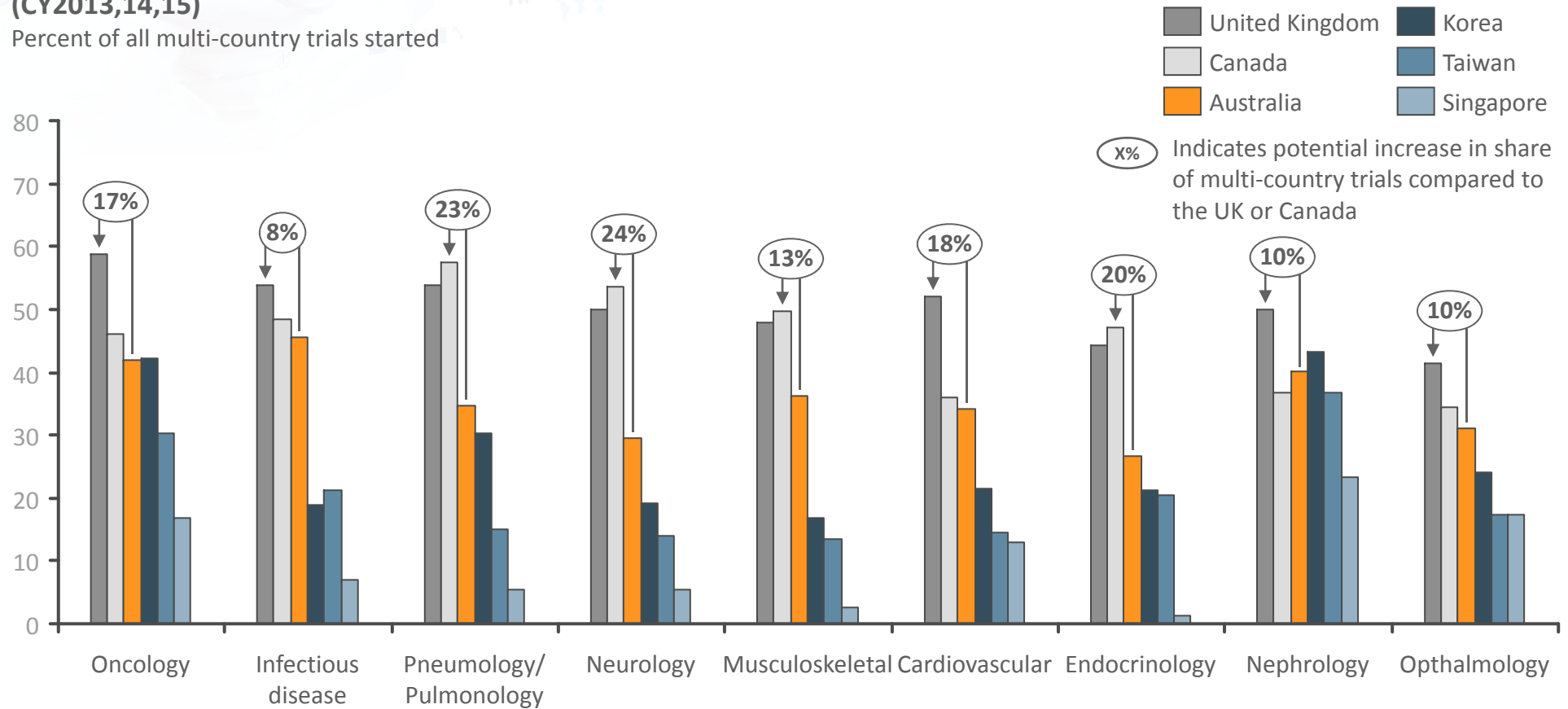


Australia is globally competitive in a number of complex disease areas



Share of industry sponsored drug and device multi-country trials, by country and therapeutic area*
(CY2013,14,15)

Percent of all multi-country trials started



Australian CRO Experience is Significant



- Experience across all trial phases
- Expertise in FTIH, Proof of Concept and pivotal studies
- Studies conducted to international standards and regulations
- Provide full-service trials and/or specialist services as needed
- Well networked with industry stakeholders
- Able to work with other international CRO partners and Sponsors
- Have worked with and access to complex populations

Early phase trials are supported by dedicated infrastructure systems



Specialised early phase trial units



Biobanks and specialised disease databases



Medical Research Institutes with early phase specialties



Clinical trial networks with access to leading physicians



Fast and efficient approvals



Searchable clinical trials registry accessible to the public



Early phase trials

The Approval Pathway is efficient for all trials



*Study Documents inc.
Protocol, Investigator
Brochure, Informed
Consent*

**Submission for
Ethical Review**

**Submission for Site
Governance Review**

*Legal Documents inc.
Clinical Trial Agreement,
Indemnity Agreement,
Insurance Coverage*

~ 4 to 6 weeks

Approval

< 1 Day

**Notify Regulatory
Authority (TGA)**

*4 page template form
submitted electronically*

< 10 days

**Notification
Acknowledgment**

Ethical guidelines (HREC)



- Human Research Ethics Committee (HRECs) play a central role in the Australian system of ethical oversight of research involving humans.
- HRECs review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.
- There are more than 200 HRECs in institutions and organisations across Australia.
- HRECs are guided by relevant standards. Standards include those in the [National Statement on Ethical Conduct in Human Research](#) (the National Statement) issued by NHMRC
- In 2014, c.90% of multi-center ethics approvals by NHRMC certified ethics committees were completed within 60 calendar days



Australian Government

National Health and Medical Research Council

Data quality and data acceptance in key jurisdictions



Tradition of excellence in medical research

Full range of trials conducted by local and international sponsors

Clinical data compliance with the highest international standards

National focus on continual improvement through reforms and innovation

Clinical data from trials in Australia is accepted and respected in key jurisdictions globally, e.g. FDA & EMA

AustralianClinicalTrials.gov.au



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

AustralianClinicalTrials

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Real stories



[Leslie Gilham, Breast Cancer Clinical Trial Participant, Australia & New Zealand Breast Cancer Trials Group](#)

I decided to participate in a clinical trial to not only help women today but to also help future generations. I would never want my kids to have to go through what I did.

[View all stories](#)

Latest Information

Real story videos of participants and researchers now published! **New**
You can now subscribe and receive alerts of new trials **New**
Australia celebrates International Clinical Trials Day! **New**
[View the NHMRC webinar on the Human Research Ethics Application \(HREA\)](#) **New**

[Australian Government Clinical Trials Initiatives](#)

Updated 1 August 2016
An overview of current activities to improve the clinical trials environment



[What is a clinical trial](#)

How clinical trials test



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

Helping yourself and



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

Who to talk to and



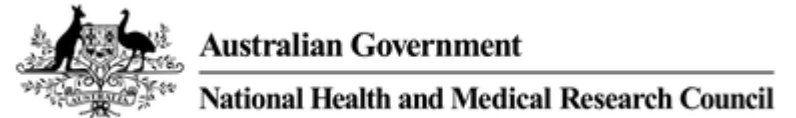
[Consumer guide to clinical trials](#)

Consumers Health

[eLearning Modules](#)



AKESA Pharma



NHMRC Clinical Trials Centre - University of Sydney





MTPConnect
MedTech and Pharma Growth Centre

MEDICAL TECHNOLOGIES AND PHARMACEUTICALS INDUSTRY
INNOVATION GROWTH CENTRE

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The Industry Growth Centres are an Australian Government Initiative



Australian Government
Department of Industry,
Innovation and Science

Industry
Growth
Centres

Further information about the
Industry Growth Centres Initiative is
available at [www.business.gov.au/
industrygrowthcentres](http://www.business.gov.au/industrygrowthcentres)