

MTP *Connect*

MedTech and Pharma Growth Centre

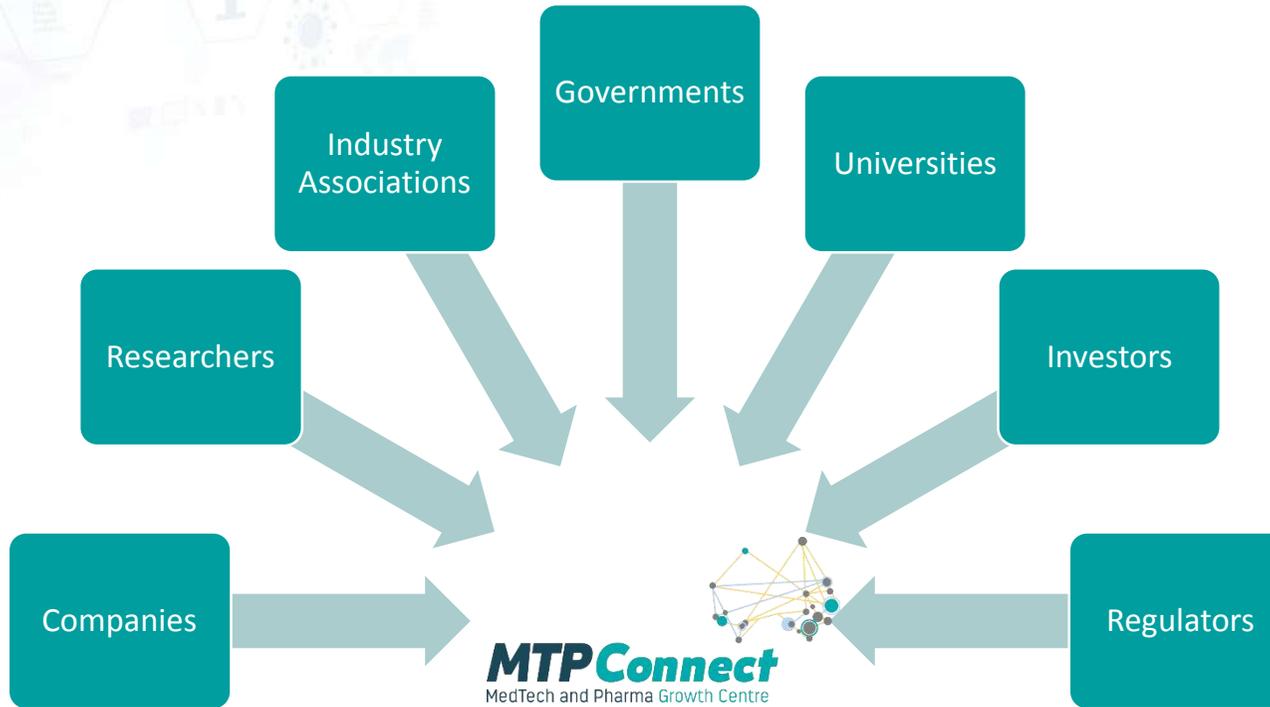
Australia: A Dynamic Environment for Conducting Clinical Trials

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



Australian Government
Department of Industry,
Innovation and Science

Industry Growth Centres



OUTCOMES



Regulatory reform



Improved access to global supply chains and international markets



Improved engagement between research and business



Improved management and workforce skills



Our three pillars

Taking Action

Undertaking highly targeted actions to foster connection and collaboration

1

Independent Voice

Listening to the sector to provide an independent voice to shape policy and regulatory renewal, and influence the direction of funding

2

Projects Investment

Jointly funding targeted, sector-led projects to address identified constraints and gaps

3

Our mandate as an Industry Growth Centre is focused on four key areas:



Increasing collaboration and commercialisation across the sector



Improving management and workforce skills

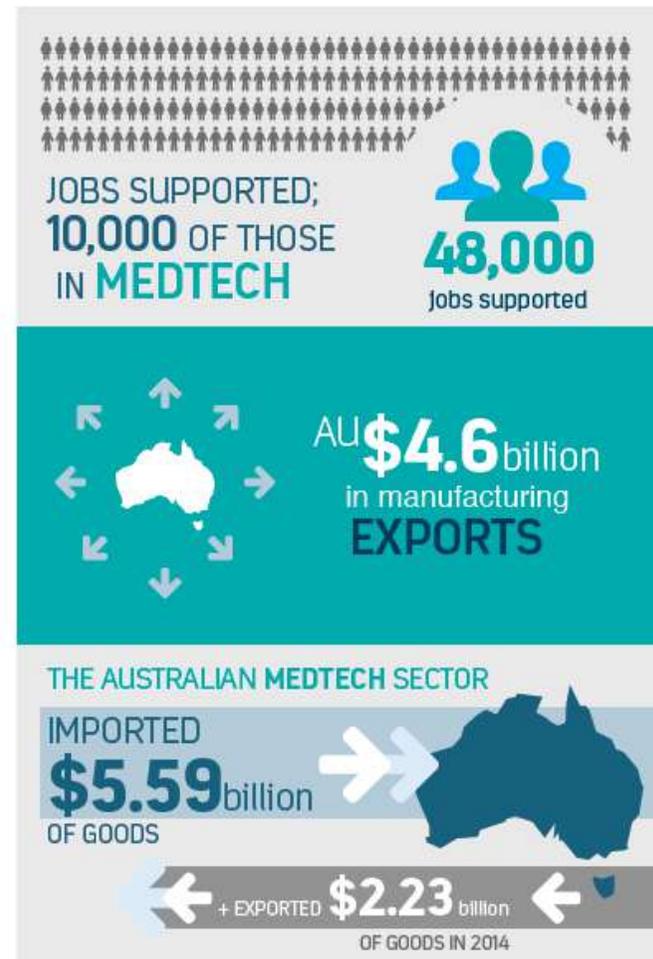


Improving access to global supply chains and international markets

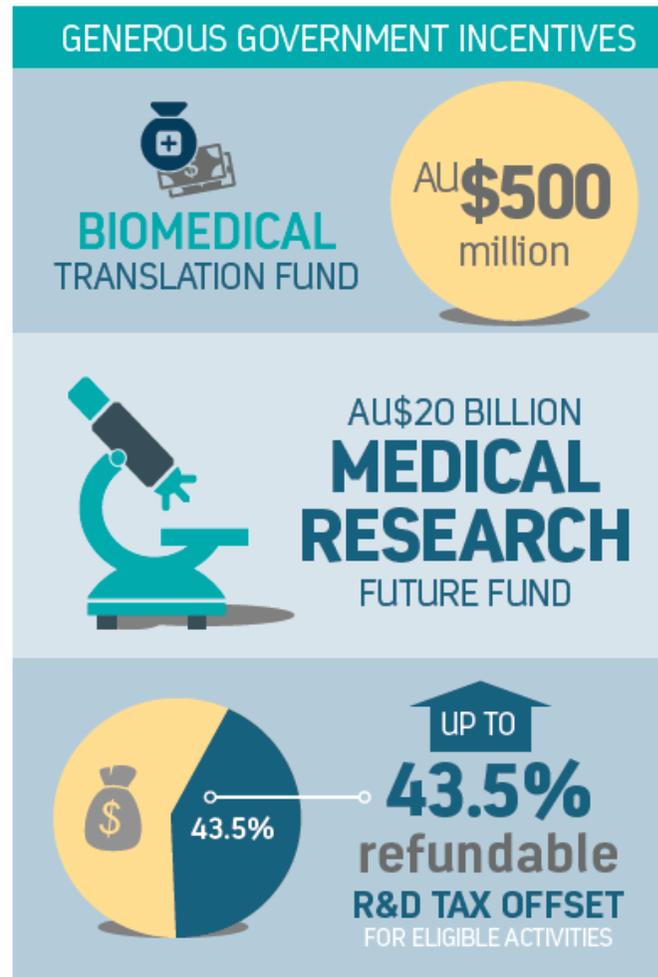


Optimising the regulatory environment

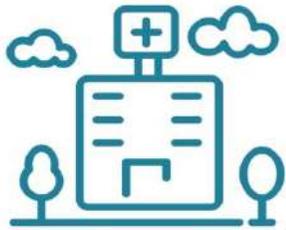
The Australian MTP Sector



The Australian MTP Sector



Megatrends impacting the MTP sector



The chronic burden



Consumer control



Precision healthcare



Digital evolution



Integrated care models



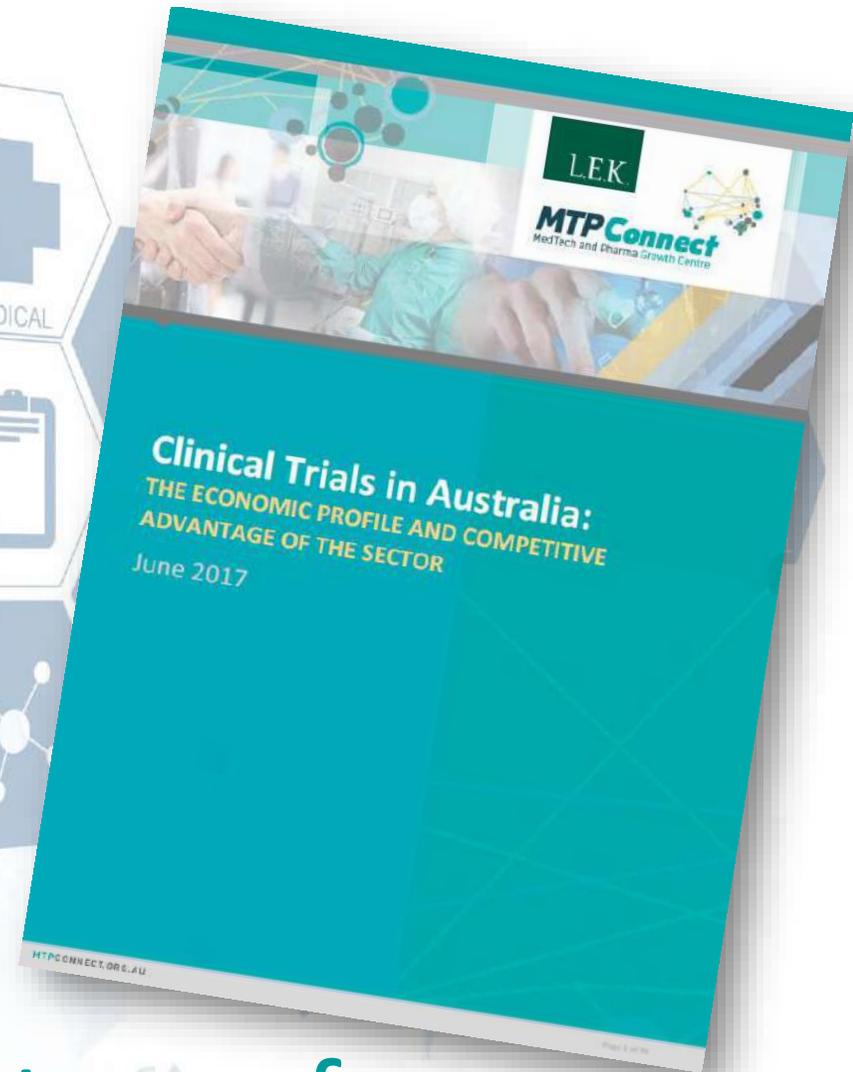
Developing markets



Global biosecurity



Report:
The Economic Profile
and Competitive Advantage of
Clinical Trials in Australia



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)
- Ethnically 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 Clinical Trial Sector in Australia is a Significant Contributor



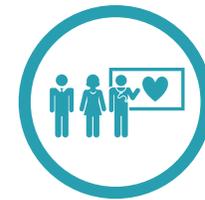
c.1,360

TRIALS STARTED in
2015 (ANZCTR)



\$1.1b

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



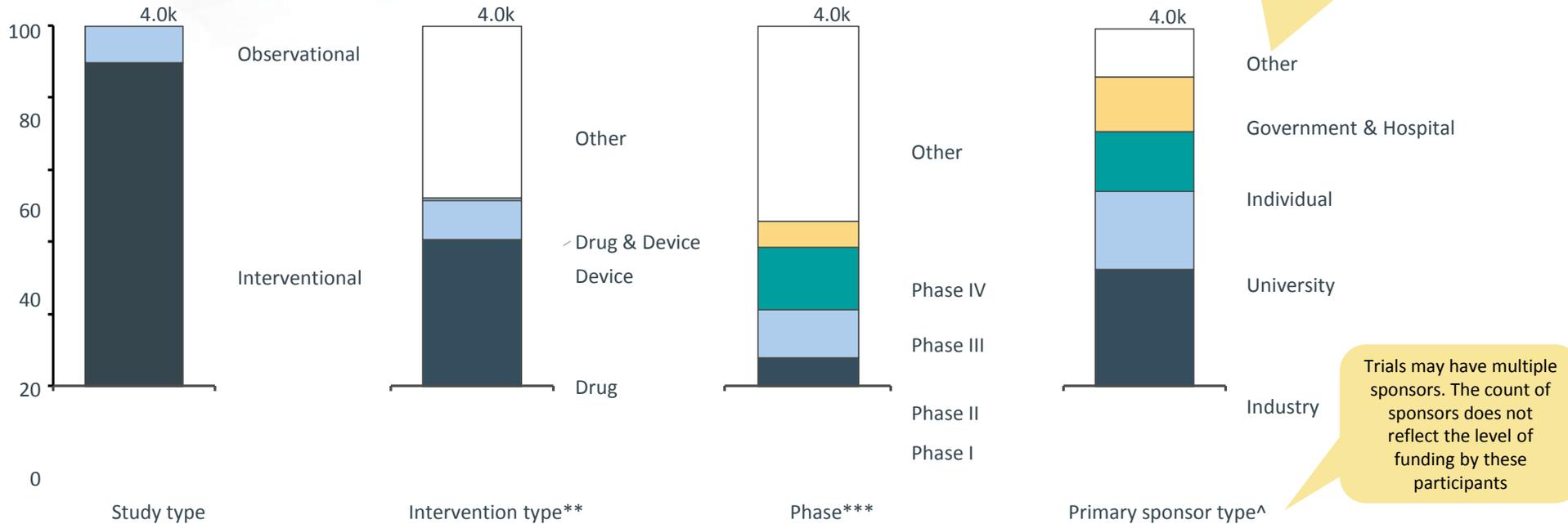
c.6,900

JOBS SUPPORTED,
largely tertiary
qualified

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

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

Percent



ClinicalTrials.gov records University trials as 'Other'

Trials may have multiple sponsors. The count of sponsors does not reflect the level of funding by these participants

Note: * Excludes 'Withdrawn' trials and duplicate entries. Where trials had a 'NULL' actual start date, the anticipated start date was used; ** Drug includes all 'drug' or 'biological' intervention types only (excluding any 'device' intervention types). Device includes 'device' intervention types only (excluding any 'drug' or 'biological' intervention types). Drug & Device includes both 'drug' and/or 'biological' and 'device' intervention types. Other includes: 'Behavioral', 'Procedure', 'Genetic', 'Radiation', 'Dietary Supplement', (not exhaustive) and trials where no intervention type was specified; *** Phase I includes 'Phase 0', Phase II includes 'Phase 1 / Phase 2', Phase III includes 'Phase 2 / Phase 3' and Phase IV includes 'Phase 3 / Phase 4'. Other includes 'Not Applicable' or 'N/A', and trials with no phase indicated; ^ Industry includes: 'Industry' and 'Commercial sector/Industry'. Government & Hospital includes: 'Government body', 'NIH', 'U.S. Fed' and 'Hospital'. Other includes 'Other', 'Other Collaborative groups', 'Charities/Societies/Foundation' and trials where no sponsorship type was specified

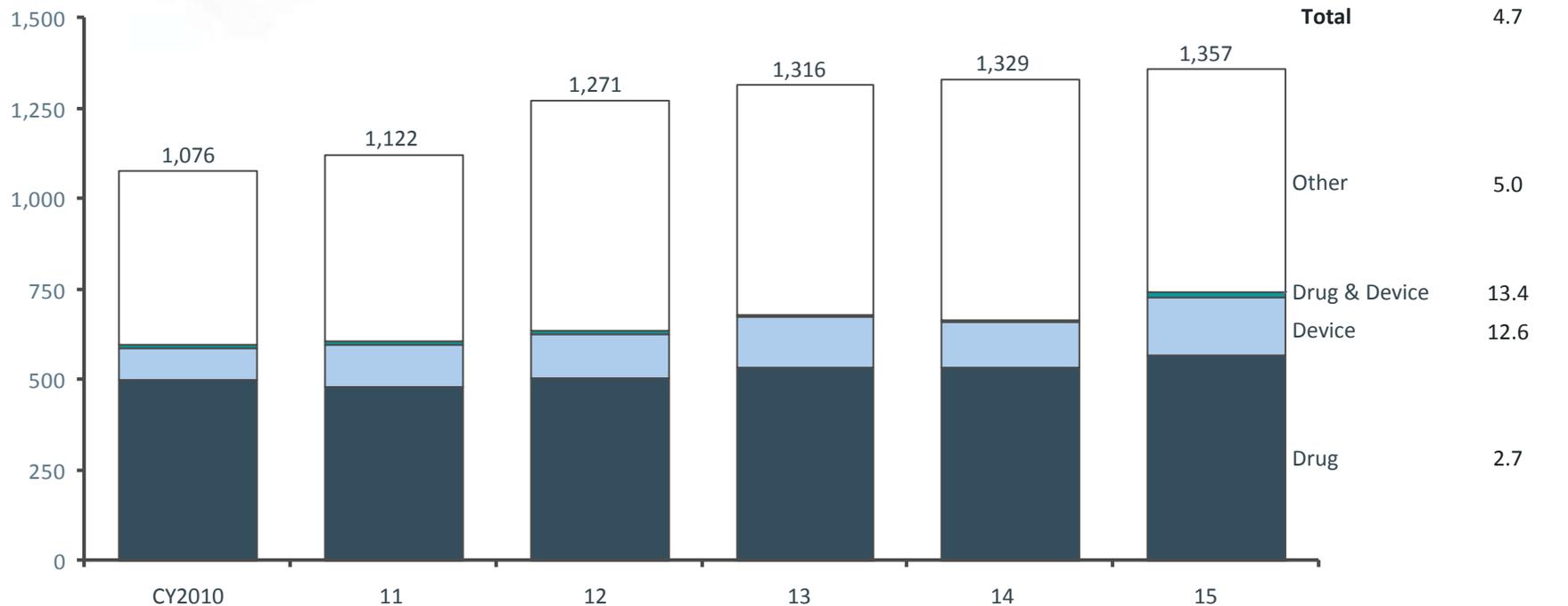
Source: ANZCTR and ClinicalTrials.gov – combined by ANZCTR; L.E.K. analysis

Drug and device trials make up the majority of studies. Device and other trials have highest growth



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

Number of trials started



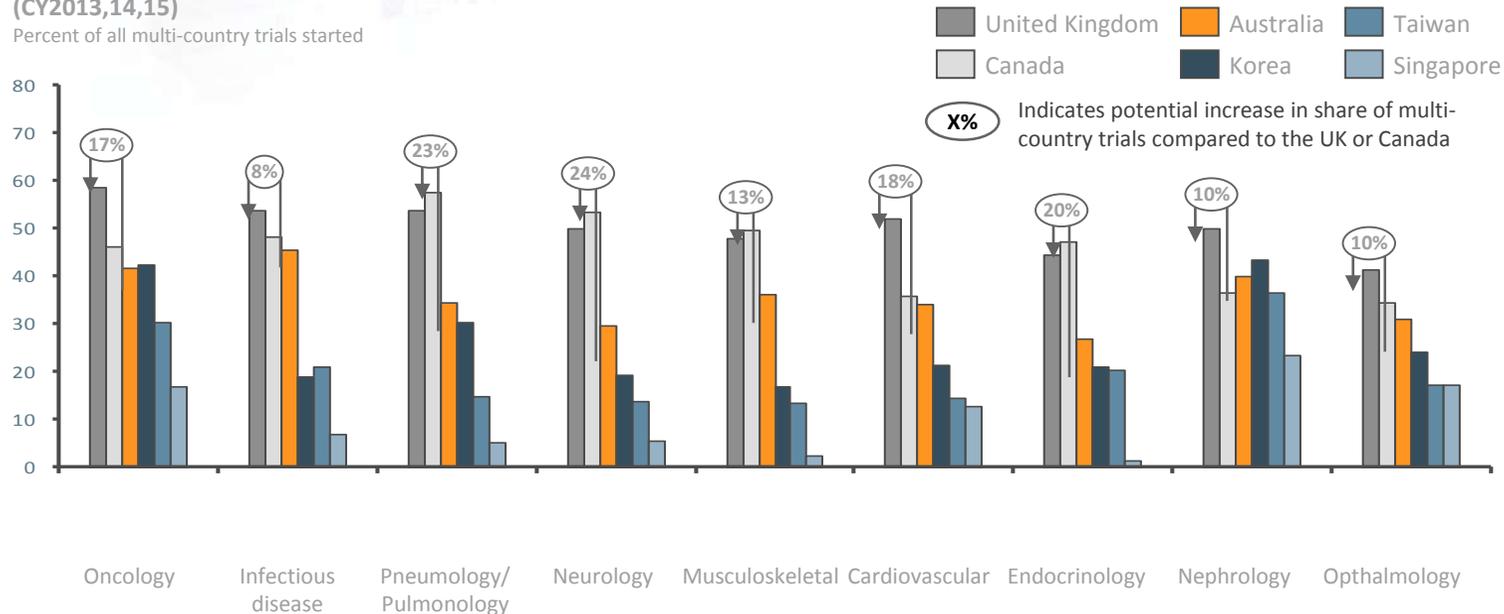
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Source: ANZCTR and ClinicalTrials.gov – combined by ANZCTR; L.E.K. analysis

Australia is 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

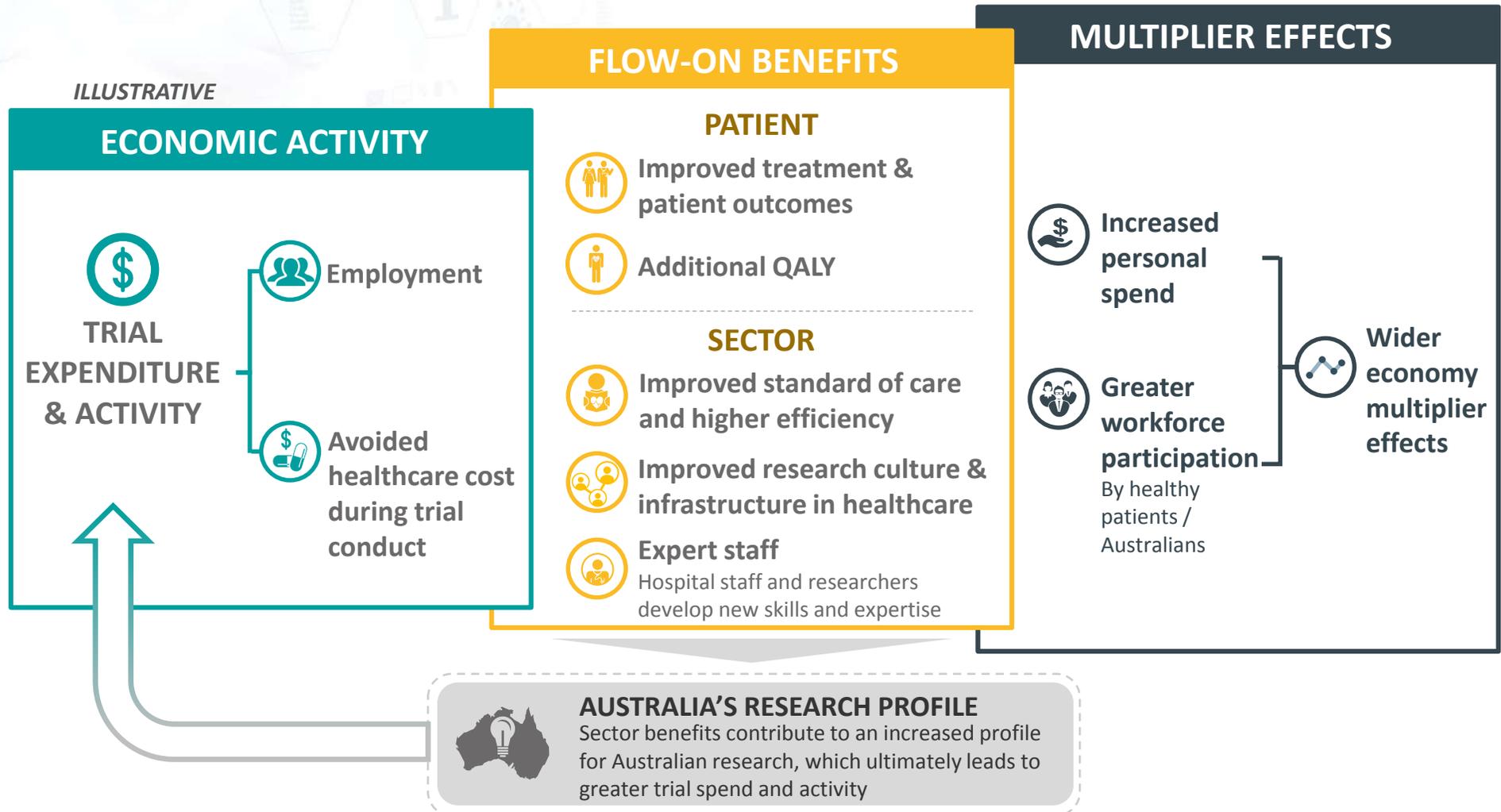


Therapeutic Area	Number of multi-country trials started in Australia
Oncology	294
Infectious disease	84
Pneumology/Pulmonology	65
Neurology	49
Musculoskeletal	43
Cardiovascular	40
Endocrinology	38
Nephrology	12
Ophthalmology	9

Note: ** Includes Drug, Device, and Drug & Device intervention types only. Includes Industry and Industry & Other sponsored trials only. 'Withdrawn' trials are excluded. Multi-country trials are defined as having planned recruitment in more than three countries. Therapeutic areas were determined using a search of key words within the 'conditions' field in the clinical trial database – excludes trials where multiple therapeutic areas were found

Source: ClinicalTrials.gov (as at 06/02/2017); L.E.K. analysis

Economic activity also drives flow-on benefits and multiplier effects



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

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.



Australian Government

National Health and Medical Research Council

Data quality and Data acceptance in key jurisdictions

- Australia's tradition of excellence in medical research has made it a key player in global healthcare
- International and local pharmaceutical, biotechnology and medical device companies conduct a full range of clinical trials in Australia
- Clinical data which complies with the highest international standards
- Data acceptance in key jurisdictions globally eg FDA, EMA – proven track record
- A national focus on continuous improvement through government reform and policy innovation



AKESA Pharma



Australian Government



Australian Trade and Investment Commission



Australian Government

National Health and Medical Research Council

NHMRC Clinical Trials Centre - University of Sydney



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News



22 Nov 2016

'Speed-Dating' Event To Unite Students And Industry

More than 150 university students from across Victoria have signed up to 'Medtech & Biotech Mingle Melbourne', a free industry event to help employers tap into emerging talent.

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17 Nov 2016

IMNIS Wins National Collaboration Award

The IMNIS mentoring scheme – a recipient of the MTPConnect Project Fund Program – has won the 2016 Best Higher Education and Training Collaboration Award at the Business/Higher Education Round Table (B/HERT) national awards.

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Featured



MTPConnect Unveils 10-Year Plan To Boost Competitiveness Of Medtech, Biotech And Pharmaceutical Sector

Australia--Monday 25th July, 2016: MTPConnect--The Medical Technologies and Pharmaceuticals Industry Growth Centre--today launched its Draft Sector Competitiveness Plan (Draft SCP), a 10-year strategic plan to boost the innovation, productivity and competitiveness of Australia's medical technology, biotechnology, and pharmaceutical (MTP) sector.

[→](#)



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)