Australia: A Dynamic Environment for Conducting Clinical Trials
MTPConnect’s goal is to accelerate the growth of Australia’s MTP sector

- 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

1. Taking Action
   Undertaking highly targeted actions to foster connection and collaboration

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

3. Projects Investment
   Jointly funding targeted, sector-led projects to address identified constraints and gaps

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

### Companies
- 50 Pharma
- 400 Biotech
- 500 Medtech
- >100 ASX listed

### Market Value
- AU $85 billion

### Gross Value Added
- AU $4.4 billion
- 34.4% of that in Medtech

### Jobs Supported
- 10,000 of those in Medtech
- 48,000 jobs supported

### Market Value Added
- AU $4.6 billion in manufacturing exports

### imported
- AU $5.59 billion of goods

### exported
- AU $2.23 billion of goods in 2014
The Australian MTP Sector

- **Ranked TOP 5**: In biotech innovation, three years running in Scientific American’s WorldView.
- **AU $775 million**: Public spending on R&D.
- **AU $630 million**: Industry spending on R&D.

**Generous Government Incentives**

- **AU $500 million**: Biomedical Translation Fund.
- **AU $20 billion**: Medical Research Future Fund.
- **Up to 43.5%**: Refundable R&D Tax Offset for eligible activities.
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

- TRIALS STARTED: c.1,360 in 2015 (ANZCTR)
- GROSS EXPENDITURE: $1.1b on all ongoing trials in 2015
- JOBS SUPPORTED: c.6,900, 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)

- **Interventional**
  - Drug & Device
  - Device
  - Drug
  - Phase I
  - Phase II
  - Phase III
  - Phase IV
  - Other

- **Observational**

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/Foundations’ 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

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

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

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>United Kingdom</th>
<th>Australia</th>
<th>Taiwan</th>
<th>Canada</th>
<th>Korea</th>
<th>Singapore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious disease</td>
<td>17%</td>
<td>6%</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Neurology</td>
<td>23%</td>
<td>24%</td>
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<tr>
<td>Pneumology/Pulmonology</td>
<td>24%</td>
<td>4%</td>
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<tr>
<td>Cardiovascular</td>
<td>13%</td>
<td>18%</td>
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<tr>
<td>Endocrinology</td>
<td>10%</td>
<td>20%</td>
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<tr>
<td>Musculoskeletal</td>
<td>20%</td>
<td>10%</td>
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<tr>
<td>Oncology</td>
<td>17%</td>
<td>8%</td>
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<td></td>
<td></td>
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<tr>
<td>Nephrology</td>
<td>13%</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>17%</td>
<td>10%</td>
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</tbody>
</table>

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

**ECONOMIC ACTIVITY**
- TRIAL EXPENDITURE & ACTIVITY
  - Employment
  - Avoided healthcare cost during trial conduct

**FLOW-ON BENEFITS**

**PATIENT**
- Improved treatment & patient outcomes
- Additional QALY

**SECTOR**
- Improved standard of care and higher efficiency
- Improved research culture & infrastructure in healthcare
- Expert staff
  - Hospital staff and researchers develop new skills and expertise

**MULTIPLIER EFFECTS**
- Increased personal spend
- Greater workforce participation
  - By healthy patients / Australians
- Wider economy multiplier effects

**AUSTRALIA’S RESEARCH PROFILE**
Sector benefits contribute to an increased profile for Australian research, which ultimately leads to greater trial spend and activity
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

Submission for Ethical Review

- Approval
  - < 1 Day

Notify Regulatory Authority (TGA)

- < 10 days

Notification Acknowledgment

~ 4 to 6 weeks

Submission for Site Governance Review

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

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

- 4 page template form submitted electronically

< 10 days
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.
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