Global Drug Development: Keeping Australia Competitive

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International Clinical Research Operations &
Oncology General Monitoring Organisation
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The business of global drug development is changing

Global competition intense: Australian activity falling

What would Australia lose?

How can Australia be more competitive?
The business of global drug development is changing

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Global Drug Development
The Business of Global Drug Development

0 yrs | 2–3 yrs | 4–6 yrs | 6–9 yrs | 8–12 yrs | 10–15 yrs

Discovery
Pre-clinical
Phase I
Phase II
Phase III

Marketing Application
PBAC
Cabinet

Risk Mgmt →

Start Research:
• Patent commence
• Difficulty feeding pipelines
• Academic collaborations

Drug on Market:
• Re-coup cost before patent expiry
• Generics commence on patent expiry
• Drugs on patent critical revenue stream
Global Drug Development

The Business of Global Drug Development

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<th>0 yrs</th>
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- Compound Success Rate by Stage: 10,000, 250, 5
- Estimated costs: $750 million - $1 billion

Risk Mgmt → Marketing Application → PBAC → Cabinet
Global Drug Development
The Business of Global Drug Development

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Discovery
Pre-clinical
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Phase III

Marketing Application
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Risk Mgmt

SPEED TO MARKET CRITICAL:
$3 Million/day in lost sales every day late (if $1 Billion/year)
Changing global environment for drug development

- More data needed to get drugs approved
  - Global tightening of regulatory policy
  - Society expectation of more effective and safer medicines
  - Reimbursement tightening globally

- Attrition of new drug candidates continues to increase

- Rapid escalation of the costs of R&D

- Blockbuster ("one size fits all") → Targeted
### Global Drug Development

**The Business of Global Drug Development**

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**Clinical Trials**

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Since early 1990’s:
- Global Recruitment
- Central Laboratory
- Paper Case Report Form
- Intensive On-Site Monitoring
- 100% Source Data Verification (SDV)

In the last decade:
- Metrics – speed, capacity, quality, cost
- Countries - BRIC up, traditional down
- Biomarkers/P’Genetics/ECGs/Diaries
- Electronic Data Capture – faster DBL
- Remote Monitoring
- Risk based SDV

Risk Mgmt → PBAC → Cabinet
The business of global drug development is changing

Global competition intense: Australian activity falling

What would Australia lose?

How can Australia be more competitive?
Global Drug Development
Global Competition is Intense

June 2007 to June 2009: world commencements grew 3%, Australia fell 33%

Clinical Trials: Australia and the World, indexed to 2000

Index (2000 = 100)

source: clinicaltrials.gov 26-Aug-09
Global Drug Development
Global Competition is Intense

Three consecutive years of decline in number of new trials – not seen before!

Number of New Clinical Trials

Source: Therapeutic Goods Administration Half-Yearly Performance Report, July - December 2010, Clinical Trials (Medicines)
Global Drug Development
Global Competition is Intense

Phase III greatest rate of decline, Phase II flat, Phase I down

CTN Data: Number of New Trials by Phase

- Phase I (Ph I)
- Phase II (Ph II)
- Phase III (Ph III)
- Phase IV (Ph IV)

Number of new Trials

Global Drug Development

Global Competition is Intense

**Australia’s Scorecard?**

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<td><strong>Speed</strong></td>
<td>• Rapid start up, rapid patient recruitment</td>
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<tr>
<td><strong>Recruitment Capacity</strong></td>
<td>• Reliably recruit patients committed, size of patient contribution</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>• ICH Good Clinical Practice, medical expertise, translational expertise</td>
</tr>
<tr>
<td><strong>Cost (Value)</strong></td>
<td>• cost (per patient including labs), efficiency (pts/site; pts/CRA)</td>
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What would Australia lose?

How can Australia be more competitive?
Global Drug Development

What would Australia Lose?

- **Direct Benefits**
  - Patient early access to new therapies
  - Significant amount of trial activity:
    - Funding for staff and resources
    - Offset patient costs in health system
  - Local and Global Research

- **Indirect Benefits (“spill-over”)**
  - Indirect funds for academic research
  - Latest clinical evidence into clinical practice
  - Expertise in health system
Global Drug Development

What would Australia Lose?

- Significant trial activity and investment

  - $540 Million into health system per annum (best estimate)
    - ABS 2006-07 and MA Economic Survey*

  - More than 1,097 trials/projects

  - More than $260 Million into health system per annum
    (only n=23)
    - PIC RDTF Benchmark Data 2008 Activity**

* ABS: $587 million invested in 2006-07; MA Economic survey, 89% invested in clinical trials

** n = 23 global companies 2008 PIC RDTF Benchmarking Data – global trials/projects
Global Drug Development

What would Australia Lose?

- Significant trial activity

Level and Description of Activity in Australia - 2008

Global companies

Australian companies

* n = 23 global companies; n = 10 Australian companies  2008 PIC RDTF Benchmarking Data – global trials/projects*
Global Drug Development

What would Australia Lose?

- Local and Global Research

Global Companies: Type of R&D in Australia During 2008

- Basic/Discovery: 9%
- Preclinical: 11%
- Investigator Initiated Trials: 32%
- Clinical Trials: 48%

50% Locally Initiated Research
50% Global Clinical Trials

* n = 23 global companies 2008 PIC RDTF Benchmarking Data – global trials/projects
Global Drug Development

**What would Australia Lose?**

- **Significant trial activity at sites in Australia**
  
  - 70% of trials/projects at typical study site*  
  - 50% of positions at typical study site*  
    - 16% investigator  
    - 72% study coordinator/other roles  
    - (across just 187 sites this was 828 positions)

* *Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research: March 2009*
Global Drug Development
What would Australia Lose?

- Value as reported by Investigators*

  - Early patient access to new medicines
  - Enhanced uptake of new evidence into clinical practice
  - Improved standard of care - better health outcomes
  - Source of funds to supplement academic projects
  - Practical experience for researchers/study staff
  - Global recognition for Australian researchers
  - Retaining researchers in Australian health system

* Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research: March 2009
Global Drug Development
Keeping Australia Competitive

- The business of global drug development is changing
- Global competition intense: Australian activity falling
- What would Australia lose?
- How can Australia be more competitive?
How can Australia be more competitive?

- Play to our strengths and be smart
- All stakeholders need to work together
- Need national leadership and coordinated action
  - Natural ability no longer good enough
CLINICALLY COMPETITIVE: BOOSTING THE BUSINESS OF CLINICAL TRIALS IN AUSTRALIA

CLINICAL TRIALS ACTION GROUP REPORT
MINISTERS’ FOREWORD

Australia is at the forefront of clinical research – an industry that trains and employs Australian professionals of the highest calibre – to provide world class medical treatment for life threatening and chronic illnesses. It is an industry that brings hundreds of millions of dollars annually into Australia’s health system.

Australia’s clinical trials industry has grown rapidly over the past decade. Some of our processes have not evolved to keep pace with this growth and, accordingly, need reform. This will ensure we maintain international competitiveness and secure investment so that all Australians can continue to enjoy the wide-ranging benefits to the health system that clinical trials provide.

We are very pleased to release the final report to Government of the Clinical Trials Action Group, Clinically competitive: boosting the business of clinical trials. The Australian Government endorses the report’s recommendations.

The report addresses key issues including:

- the timeliness of clinical trial approvals,
- the benefits of e-health for clinical trials,
- improving patient recruitment, and
- the level of support for clinical trials networks.

The Hon Nicola Roxon MP
Minister for Health and Ageing

Senator The Hon Kim Carr
Minister for Innovation, Industry Science and Research
CTAG Report: Improve Timeliness

<table>
<thead>
<tr>
<th>Report Ref.</th>
<th>Key points from Recommendation</th>
<th>Benefit to Australia</th>
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| A           | **National single ethical approval via HoMER adoption by July 2011;**  
  • NHMRC best practice research governance handbook  
  **30 calendar day timeframe for ethics and research governance**  
  • sponsors pay defined amount to support increased efficiency  
  **ethics review and research governance in parallel**  
  60 day maximum timeframe (incl. Lead HRECs for certification)  
  allows clock stop  
  KPIs for public hospital CEOs | Faster study start-up |
| B           | Progress reforms as per Recommendation A with  
  • university and  
  • private hospital sector | Faster study start-up |

- **Harmonisation of Multicentre Ethical Review process (HoMER)?**
- **NSW, VIC, QLD Mutual Recognition - Q2 2011**
- **Research governance process - parallel**
### CTAG Report: Improve Patient Recruitment

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<td>E, F</td>
<td>Consumer friendly trials web portal; Consumers and health professionals able register interest to be notified of trials by July 2011</td>
<td>New avenues for patient recruitment in Australia</td>
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<tr>
<td>G, H</td>
<td>GP software used to enhance patient recruitment; Consumer information via GPs and specialist offices to encourage consumers to talk to Drs about trials by July 2011</td>
<td>New avenues for patient recruitment in Australia</td>
</tr>
<tr>
<td>I</td>
<td>NHMRC identify clinical trials networks that exist by July 2011; Facilitate collaboration between academia, clinical medicine and industry</td>
<td>New avenues for patient recruitment in Australia</td>
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- Better link patients, health care providers and trials
- Increase contribution of primary care setting to trials
- Better coordinate use of trial networks that already exist
CTAG Report: Take Advantage of Developing E-Health System

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| D           | Trial monitor access to electronic health records  
  • on-site access for SDV  
  • remote access – world first | Improve monitor productivity now  
  Allow remote access for monitoring now  
  Increase trial access for regional hosp. |
|             | E-Health roll-out in Australia:  
  • Clinical research to be considered in design & implementation  
  • NEHTA at national level  
  • state/territory governments | Future opportunities for feasibility, epidemiology, patient identification for trials, etc |

- Remote Access to Patient Medical Records  
  - Novartis & Peter MacCallum Cancer Centre pilot ongoing  
- Clinical research now clear stakeholder in e-health
CTAG Report: Cost Recovery of Efficient Trials

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<td>C</td>
<td>Standard costs for all trials on cost recovery basis</td>
<td>Faster budget negotiation</td>
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<td>Independent hospital pricing authority, by July 2011</td>
<td>Faster study start-up</td>
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<td>Consistency in trial costs across Australia</td>
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- Greater certainty that health system costs covered
- Speed start-up – faster budget negotiation
- Keep cost in line with similar developed countries
- Certainty for non-industry sponsors also
CTAG Report: Progress Key Clinical Trial Issues

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<td>J</td>
<td>DIISR collate value and performance of Australian clinical trials</td>
<td>Data critical show change for global decision makers and value to Australia</td>
</tr>
<tr>
<td>K</td>
<td>Pharmaceuticals Industry Working Group (PIWG) becomes mechanism for stakeholder review of progress on implementation</td>
<td>Mechanism to ensure government implements at Ministerial level</td>
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- Pharmaceutical Industry Working Group:
  - Ministers Carr and Roxon
  - Federal Departments: Health & Industry
  - NHMRC, other groups
  - Pharmaceutical Industry:
    - Medicines Australia, Ausbiotech, Generic Medicines
Global Drug Development
Keeping Australia Competitive

- **Australia has been very successful**
  - Derived significant value
  - Faces significant challenges

- **Stakeholders are responding**
  - NSW, VIC, QLD – streamlining multi-centre trial review
  - Industry – Std Contracts, Simplify Adverse Event Reporting
  - Australian Government – CTAG Report

- **Clinical trials environment is complex**
  - Execution of recommendations is not simple
  - Ongoing stakeholder collaboration will be critical
  - Ongoing dialogue will be vital to manage change successfully
Thank you