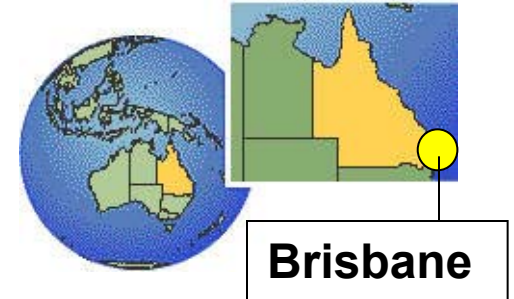




**Australia & Queensland
Clinical Drug Development
Opportunities**

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Agenda



❑ **Pharma & Biotech Landscape**

- Australia
- Queensland

❑ **Clinical Trials in Australia**

❑ **Queensland Clinical Trials Network Inc.**

❑ **Examples of QCTN Member organisations**

Australia

- ❑ Population of Australia is about 21 million
- ❑ ~60% of population concentrated in the major cities



Australia

- ❑ **States like Queensland have their own Government**
 - Responsibilities include amongst others Research & Innovation, Investment Attraction, Healthcare

- ❑ **Australian Federal Government**
 - Responsibilities include Clinical Trials Regulation & Marketing Approval of Drugs/Devices

- ❑ **Australian Regulatory Authority for regulating Medicines and Medical Devices is called TGA (~ FDA)**
 - Therapeutics Goods Aministration

- ❑ **Australian regulations consistent with ICH regulations**

Pharma and Biotech in Australia

Pharma/Devices/Nutraceuticals

Measure	1997	2005	Compound Annual Growth
Australian GDP	\$624.1 billion	\$830.4 billion	3.6%
Pharmaceutical Industry Gross Product	\$5.25 billion (~0.85% of GDP)	\$9.65 billion (~1.16% of GDP)	7.9%
Industry Revenue	\$19.02 billion	\$36.65 billion	8.5%
Industry Employment	97,578	125,901	3.2%
AUS Pharma Exports	\$1.36 billion	\$3.55 billion	12.8%
AUS Pharma Imports	\$3.77 billion	\$10.79 billion	14.1%

Source - Industry Profile: Pharmaceuticals, Nutraceuticals/Compl.Med., Med. Devices. 29 August 2006



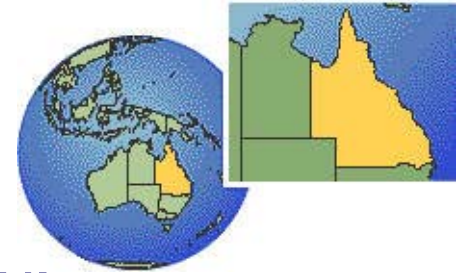
Annual revenues Australian Pharma is \$12 billion, ~ 1 % of world market and ~ 30,000 people are employed in pharmaceutical industry (Source: IBISWorld)

Biotechnology (2006)

- **427 Core biotechnology companies**
 - Market cap AUS \$ 13.31 billion
- **625 Medical device companies**
 - Market cap AUS \$ 8.47 billion
- **Increased M&A activities**
 - 45 M&A's of which 8 by overseas companies
 - Total value AUS \$ 4.1 billion
 - Monoclonal Antibodies driver for a number of deals
- **Last 5 years, 1/3 of new Australian biotechs => QLD**

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Queensland Biotechnology



“Smart State” Vision for the Industry:

By 2025

- employing over 16,000 people
- generating AUD4 billion in revenue
- AUD20 billion industry

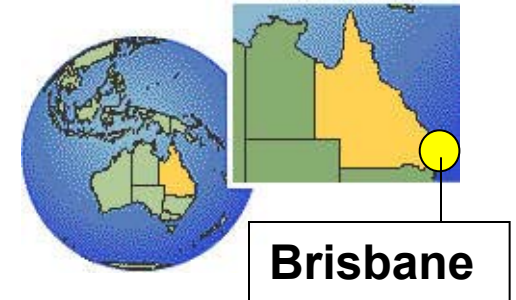
Over AUD 600 Million (>US\$ 470 M) invested by Queensland Government on Biotechnology

Infrastructure	Research Funding	Business Grants	Education/ Marketing
\$423 Million	\$152 Million	\$20 Million	\$17 Million



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Agenda



❑ Pharma & Biotech Landscape

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“Australia is #1 site to conduct Clinical Trials”

Summary of Economist Intelligence Unit Report:

“Benchmarking Study of the Characteristics of the Australian and International Pharmaceutical Industries”

September 2005

- ❑ **Independent study by the Economist Intelligence Unit**
- ❑ **Commissioned by Australian Governments**
- ❑ **Benchmarked Australian Industry versus:**
 - USA
 - UK
 - Germany
 - Japan
 - Singapore
 - India

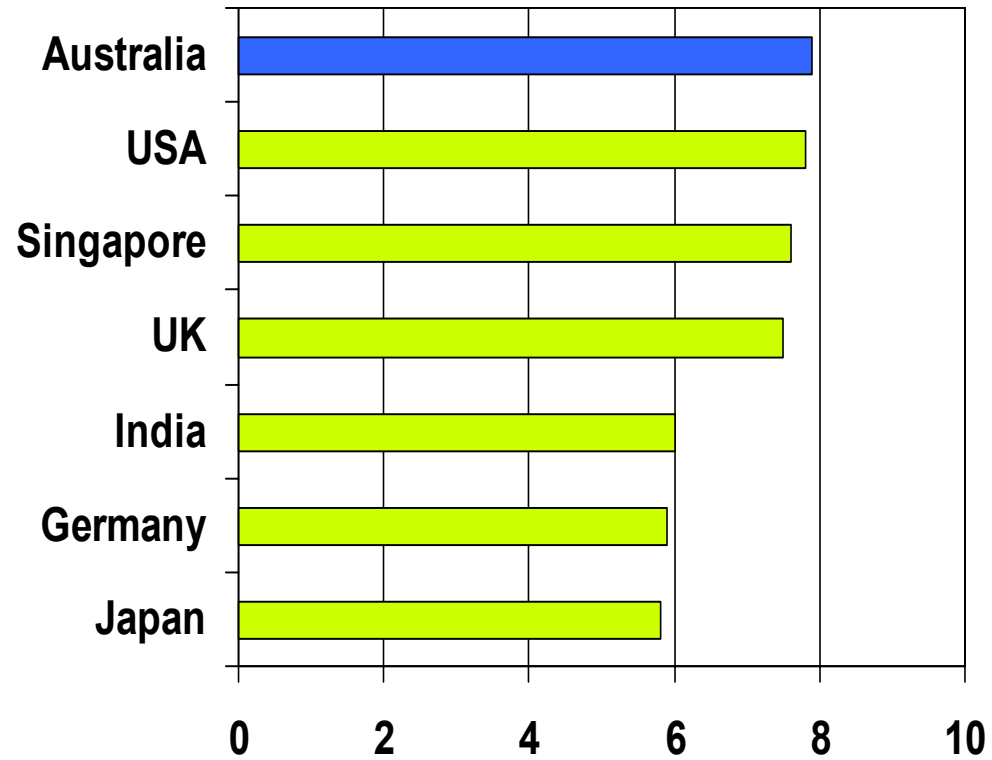


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For full report, go to www.qctn.com.au > Conducting Trials > Why Queensland?

Clinical Trials - Benchmarking

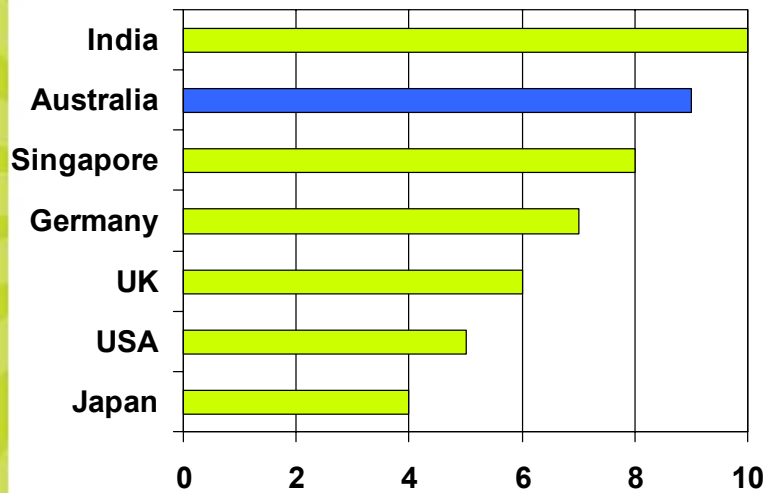
Aggregate Benchmark Scores



What is driving Australia's performance?

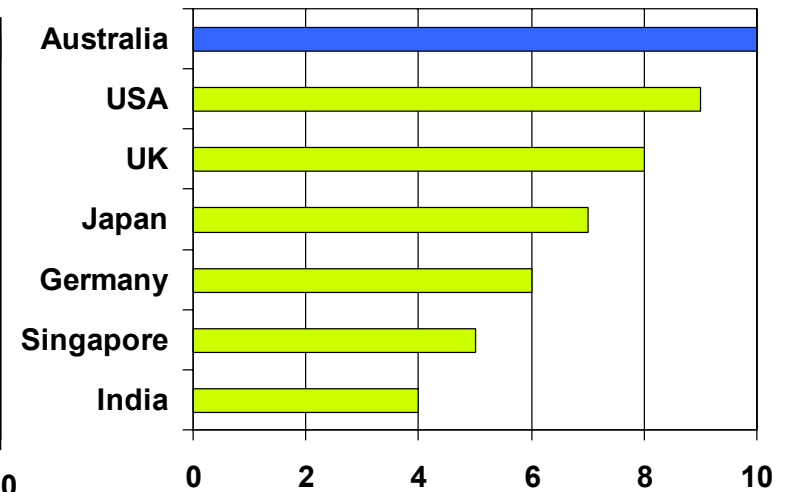
Performance is driven by low average cost per patient and high availability of research sites ...

Average cost per patient



\$6,712 (USA) to \$2,500 (India)
\$3,984 (Australia)

sites per 100,000 pop.

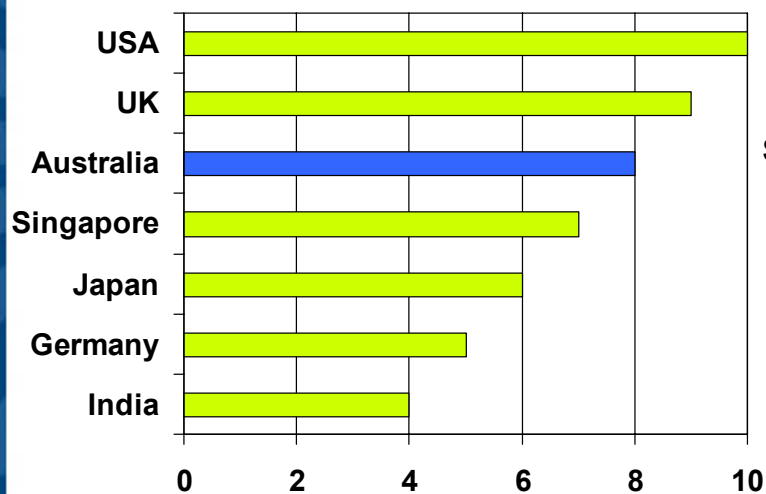


25,000 (USA) to 11 (Singapore)
2,500 (Australia)

source: CentreWatch

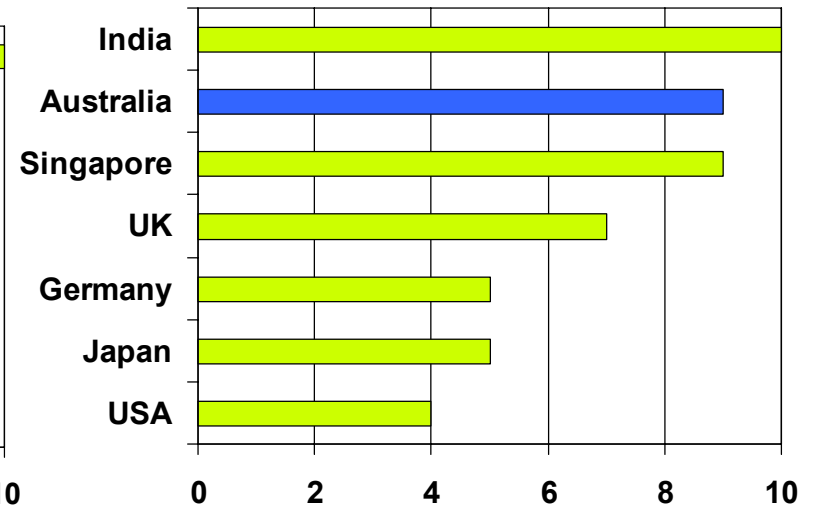
... And good participation rates and high on-time completion rates ...

patients in trials per 100,000 pop.



**3,600,000 (USA) to 3,745 (India)
20,000 (Australia)**

% Studies completed on time



**85% (India) to 10%(USA)
80% (Australia)**

source:

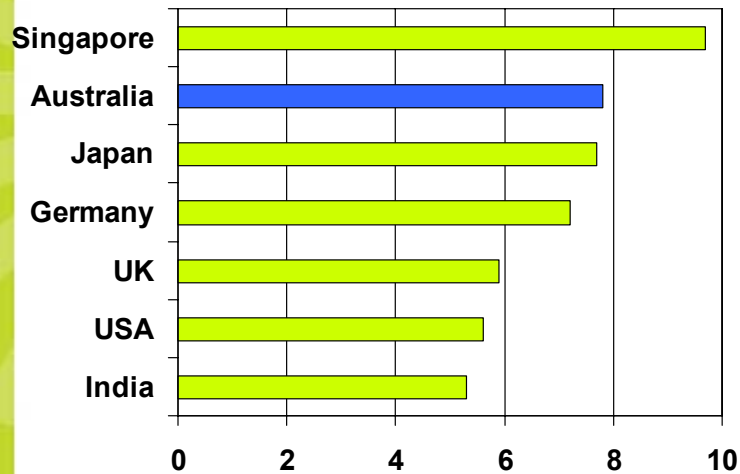
CentreWatch



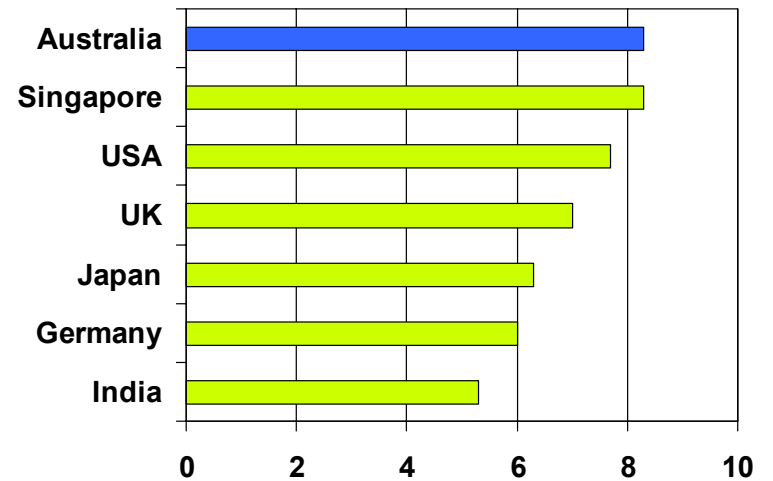
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... And a Quality WorkForce

Pharma Industry skilled professionals per 100,000 LF.



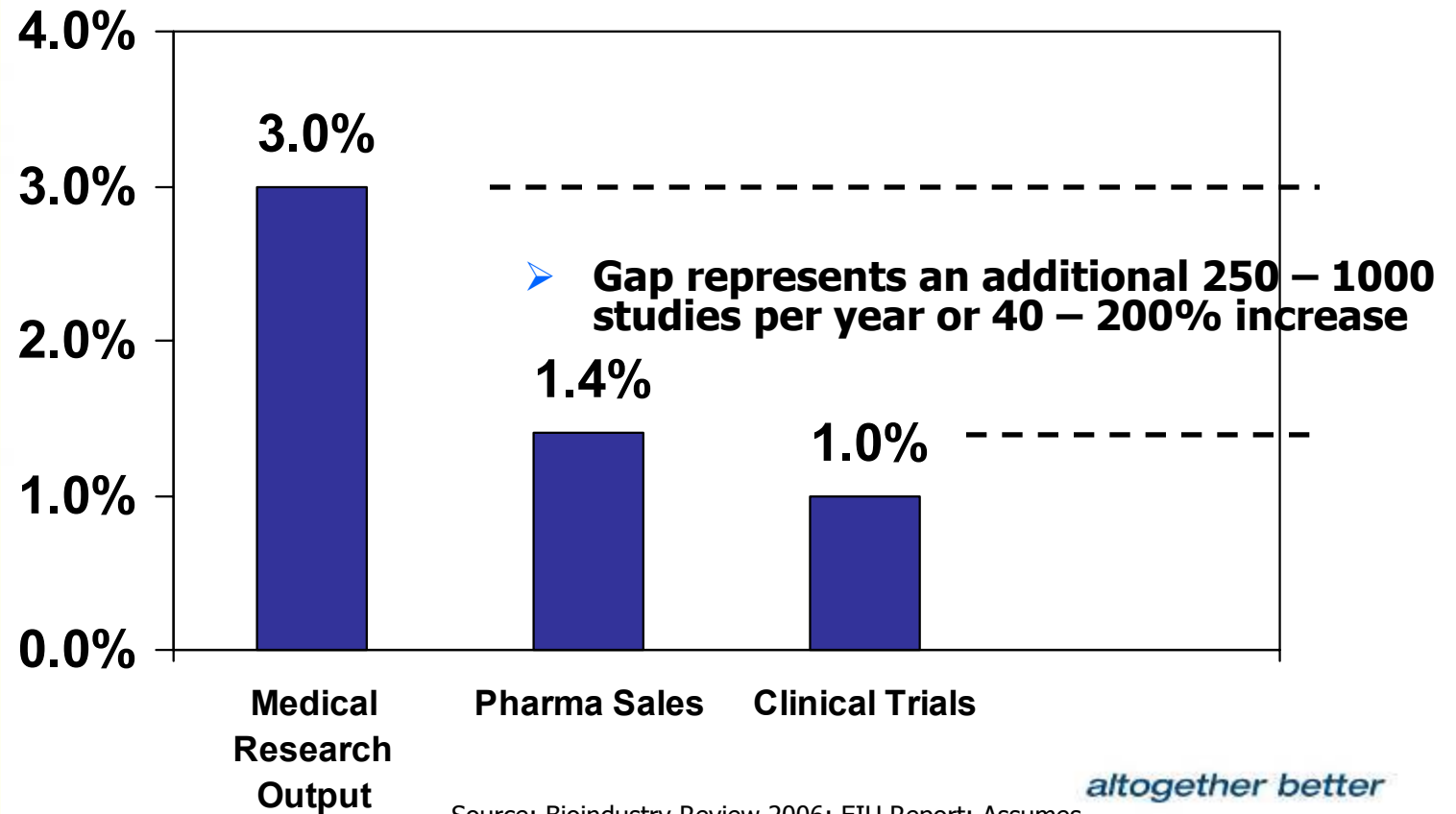
#Graduate degrees per 100,000 LF.



Other includes Phase IV, medical device, bioequivalence

Potential for more Clinical Trials in Australia

■ Share Global Market in %



Source: Bioindustry Review 2006: EIU Report; Assumes benchmark countries represent 80% of all studies

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In Summary:

- **Australia was ranked first, scoring well for**
 - Low average costs of clinical trials
 - Large amount of qualified trial sites
 - High % of clinical trials completed within allocated time
 - Highly skilled population

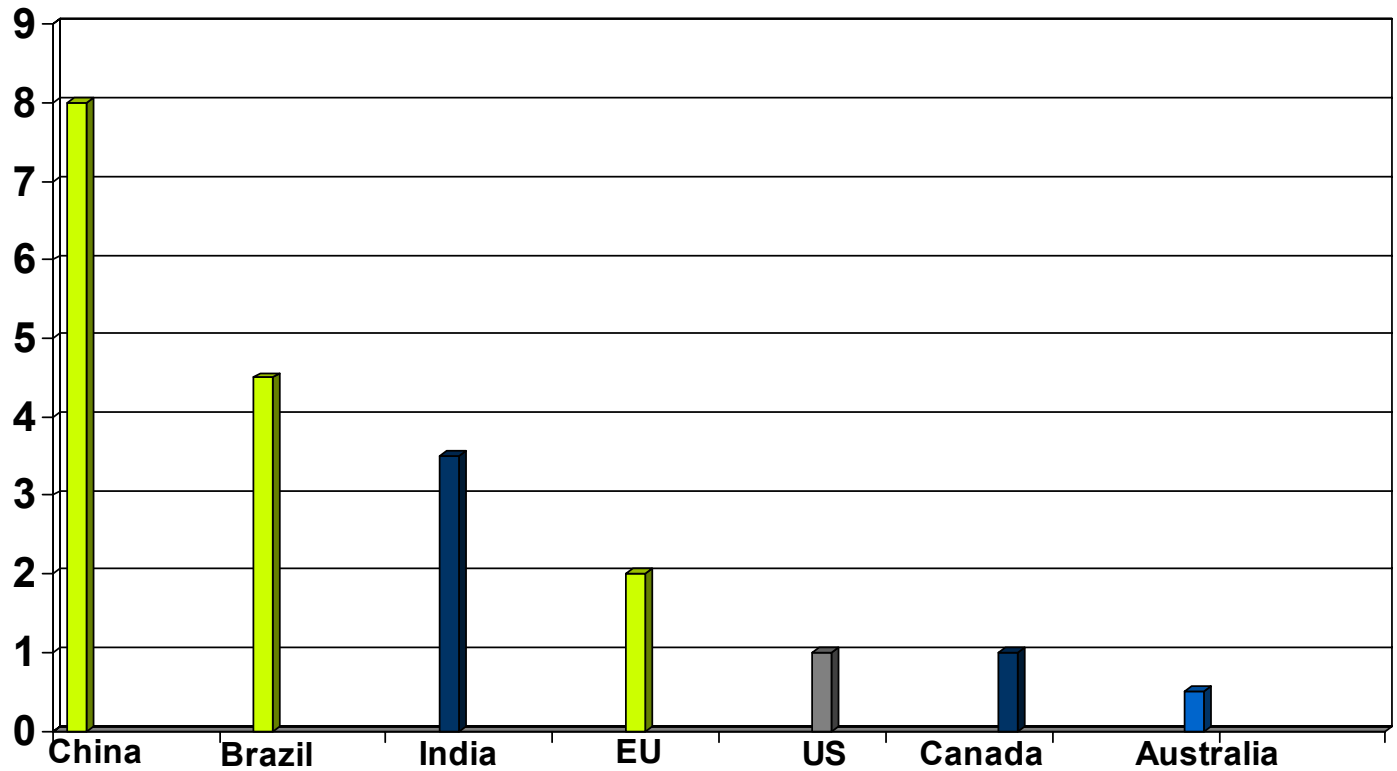
and

- **Significant potential for more clinical trials**



Clinical Trial Application Review Time

Months

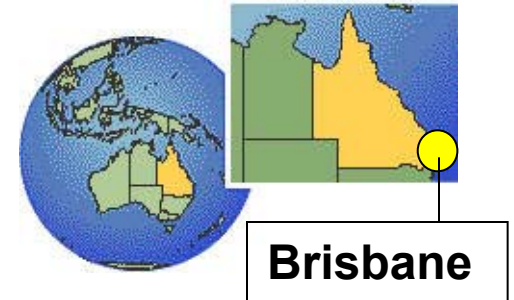


Source: Robert Maguire, MD

Clinical Trials in Australia -Considerations

Fast start - for most trials no need for an approval process (i.e. via the CTN process)	Use Australia for early phase clinical trials as a "stepping stone" for starting trials in USA & EU or consider doing Bridging trials in Australia for Japanese/Asian market
Highly skilled clinical staff (ICH-GCP) + Very modern facilities + Strong IP protection	Rigorous review of gene therapy and related therapy studies by Australian authorities
ICH-GCP mandatory for all trials	Necessary to arrange local legal representation ("sponsorship") and insurance
Cost-effective as compared to US, EU, JPN	More expensive than India or China
High % on-time completion of trials and there is capacity to do more trials	Need for multiple ethics committee approvals for multi-centre trials in some states in Australia
Multicultural population = 20 million, mainly Caucasian and Asian	Possibility of continuing seasonal studies in AUS during off-season in the Northern Hemisphere
Excellent network of preclinical, genomic & bioinformatics and early phase clinical trials service providers in Queensland (Brisbane)	Manage perceived distance and time differences (for EU and US) via good project management
Ready access to Comparator drugs, Background therapy, Standards of care, Disease tracking programs for notifiable disease outbreaks and Flu monitoring network	Medical-technical documentation such as Case Report Forms, Informed Consent Forms, etc. are all in English + recognizable units & abbreviations

Agenda



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- Queensland

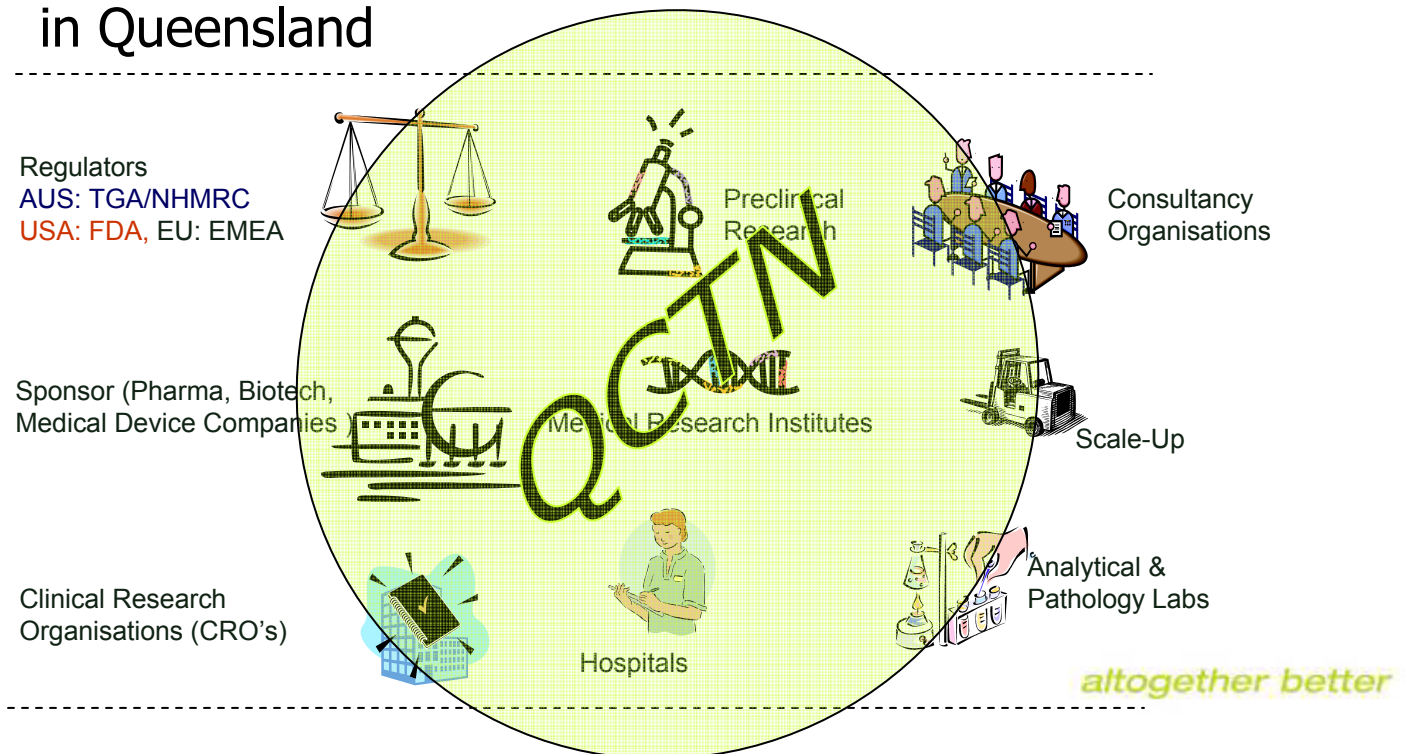
❑ Clinical Trials in Australia

❑ Queensland Clinical Trials Network Inc.

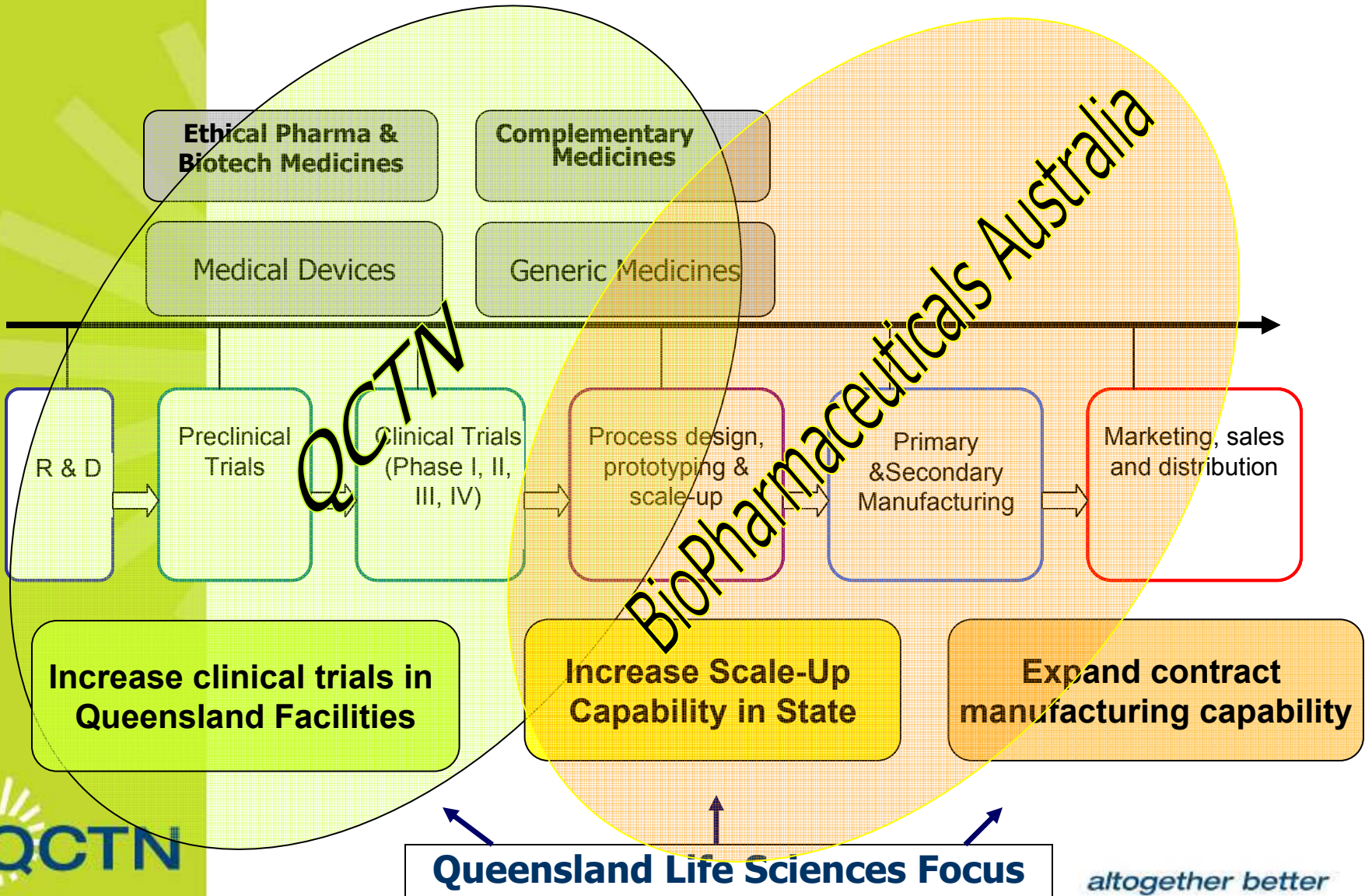
❑ Examples of QCTN Member organisations

Queensland Clinical Trials Network Inc.

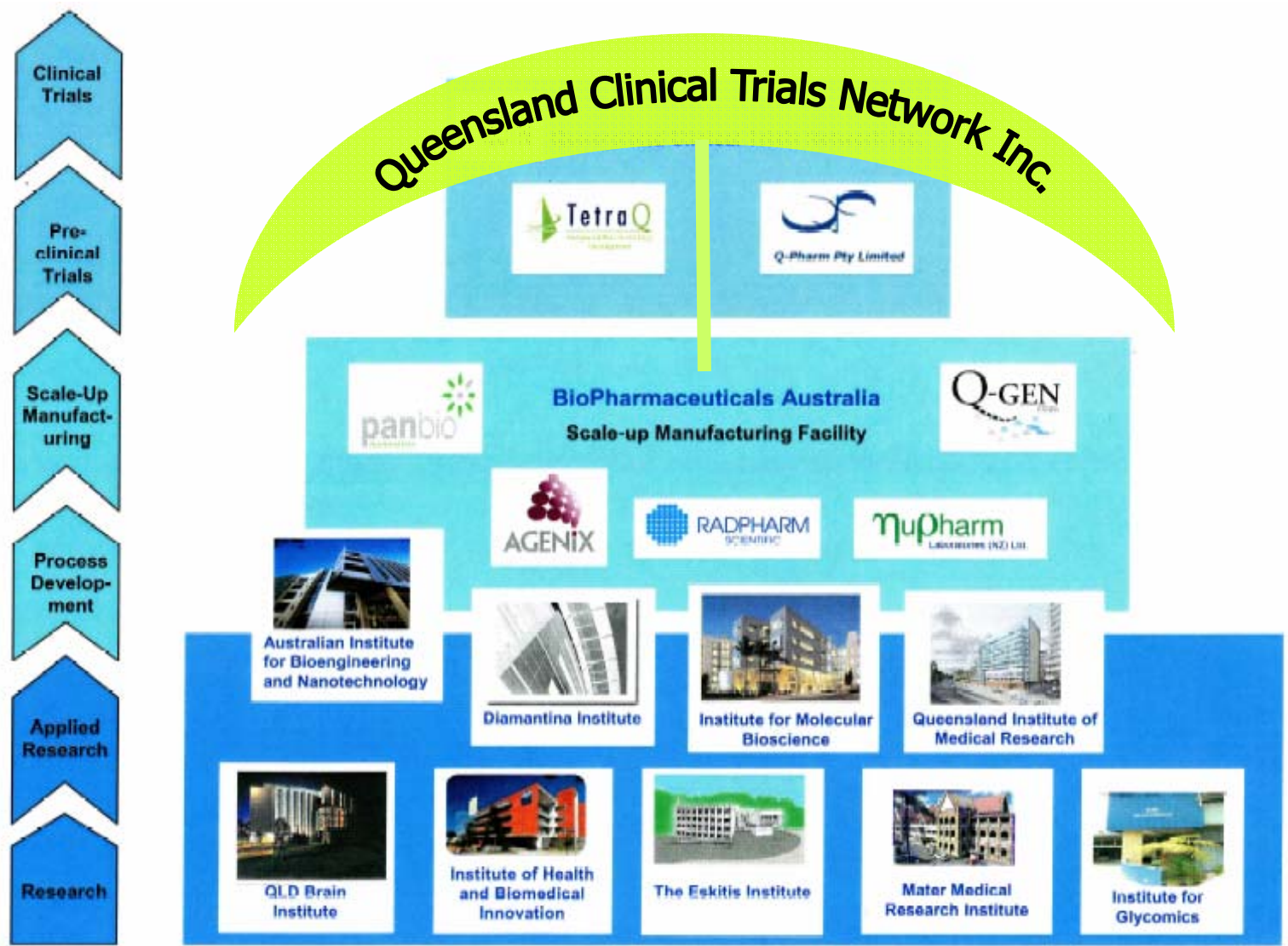
- ❑ Queensland government established QCTN in 2005
- ❑ QCTN is an independent association of clinical R&D service providers and hospitals (“umbrella organisation”) not a government entity
- ❑ Aim: To help organisations undertake clinical trial activities in Queensland



Queensland Life Sciences Approach



Comprehensive Drug Development Facilities



First world medical systems and infrastructure, highly qualified clinicians & researchers, English, diverse ethnic population ...

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Clinical Trials Capabilities of QCTN Members

- QCTN Members (>55) cover all aspects of clinical trials:
 - Clinical Network Services
 - Q-Pharm
 - ERA Consulting
 - TetraQ
 - The Wesley Research Institute
 - Core Research Group
 - QIMR
 - Genomics Research Centre
 - Emphron
 - Cairns, Nambour etc.
- CRO
- Phase I-II Unit
- Regulatory Consultancy
- Preclinical Drug Profiling
- Clinical Trials Centre
- Clinical Trials Centre
- Medical Research Institute
- Genomic & Clin. Trial Centre
- Clin. Data Mgt. & Biostat.
- Hospitals



Services for Members: Promotion

- NZBIO 2007
- Complimentary Medicine Conference
- BIO 2007, USA
- DIA Annual Meeting, USA
- ISSCR (Stem Cell), Cairns
- ISCT (Stem Cell Therapy), Sydney
- Korea, Japan, Taiwan

- CRX-07, August, Melbourne
- AusBiotech, October, Brisbane
- AAPS, USA



Australian network
to deliver your
drug development
programs



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Other Services for Members: Education

Sponsoring/Supporting

- GCP courses
- Lectures on preclinical & clinical regulations
- Clinical Investigators: Trial Design & Analysis
- BARQA activities
- Women in Biotech
- AusBiotech sessions

Investigating

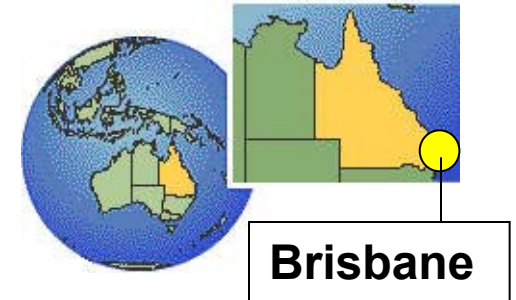
- On-line courses offered via organisations like DIA



Services for Sponsors: Help start clinical work sooner

- ❑ Arrange site visits to companies, hospitals, institutes and service providers
 - Explore opportunities for preclinical and phase zero, I or II trials in Queensland
- ❑ Match sponsors' clinical research requirements with most appropriate clinical R&D service providers
 - "Best-of-breed" approach
- ❑ Provide independent Medical-Scientific and Ethics review
 - Independent HREC ~ IRB, by August/Sept 2007
- ❑ Provide independent Biosafety review for Genetically Modified (=GM) products
 - Independent Biosafety Committee (IBC)
- ❑ Arrange local representation of company in Australia which is a legal requirement in order to start a trial

Agenda



❑ Pharma & Biotech Landscape

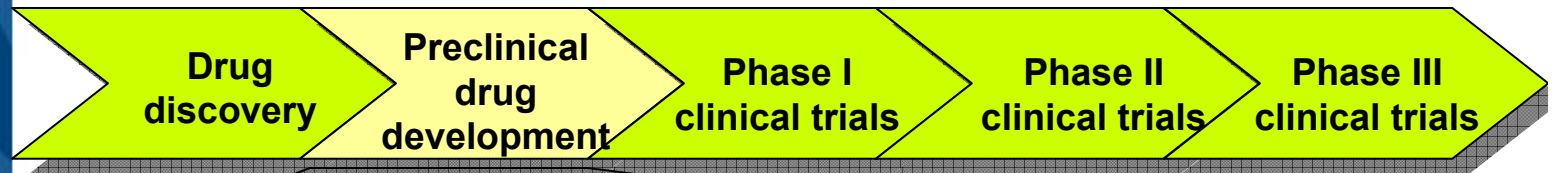
- Australia
- Queensland

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Quality Preclinical Solutions



TetraQ: Preclinical Capabilities

ADME

- ***Does drug candidate have right time constants in body (pharmacokinetics) to become a medicine for human use?***
- *in vitro* drug metabolism studies
- Bioanalytical method development & sample analysis of drugs/metabolites in biological fluids
- Fully validated to FDA requirements
- Rodent pharmacokinetic studies

Efficacy

- ***Is drug candidate effective against target disease?***
- 'Proof of concept' studies in rodent models of human disease
Validated rodent models of:
 - Pain: nociceptive, inflammatory, neuropathic
 - Multiple sclerosis/Parkinson's
 - Alzheimer's disease/Obesity/Diabetes/IBD
 - Cancer
 - Inflammation

Pharmaceutics

- ***Does drug candidate have right physical, chemical & biological properties to become a medicine for human use?***
- Physicochemical profiling (FTIR, UV, NMR, MS)
- *In vitro* absorption studies (Caco-2)
- Formulation studies
- Stability assessments

Toxicology

- ***Is drug candidate sufficiently safe to administer to humans in early stage clinical trials?***
- Toxicity testing
 - Cytotoxicity in cell lines
 - *in vitro* genotoxicity/mutagenicity assays
 - *In vivo* toxicity studies in rodents
 - *In vivo* safety pharmacology



TetraQ lab gains GLP standing

Tuesday, 10 July 2007

- **UNIVERSITY of Queensland-based contract research organisation TetraQ has been granted Good Laboratory Practice recognition from the National Association of Testing Authorities for one of its key laboratories, according to UQ. The status means that the company is now recognised to provide internationally accredited testing services to the Australian biopharmaceutical industry.**

Q-Pharm Pty Limited

- ❑ **Private company established July 2002 as a spin-out from The University of Queensland**
- ❑ **Specialists in early phase clinical trials**
 - **Phase I/II**
 - **Pharmacokinetic and Pharmacodynamic studies**
 - **Proof of Concept studies**
 - **Bio-Equivalence/Bio-Availability**
 - **Phase 0/Microdosing capability**
- ❑ **Excellent clinical research facilities**
- ❑ **Highly experienced bioanalytical laboratory**
- ❑ **Dedicated staff committed to quality outcomes for our clients**



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Q-Pharm - Location

Brisbane, Queensland, Australia

- Royal Brisbane & Women's Hospital Complex
- Co-located within QIMR



Mervyn Eadie Clinic, Outpatients Clinic

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QCTN: One-Stop Shop

QCTN Members are Pre-Clinical Service Providers, Phase I/II Units & Analytical Labs, Clinical Research Organisations, Clinics, Clinical Trial Centres, Clinical Collaborative Groups

For Members, QCTN

- Finds Sponsors
- Promotes Members
- Facilitates Collaboration
- Organises Conferences

For Members, QCTN Supports

- Institutional Biosafety Committee
- Staffing Needs
- Clinical Trial Processes & IT
- Education & Networking

For Sponsors, QCTN

- Finds Clinics/ Specialists
- Introduces Service Providers
- Identifies leads
- Provides Independent IBC & Ethics reviews



For Members, QCTN

- Arranges visits to facilities
- Meets with stakeholders
- Participates in forums
- Acts as an industry lobbyist

Pharmaceutical companies, Biotechnology companies,
Medical Device companies,
International CRO's and others

TGA, State & Federal Government,
Industry Associations, Universities &
Research Institutes



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Please remember about Australia:

- Politically stable, safe, legal and regulatory robust**
- High quality, experienced western medical expertise**
- Early clinical development phase strengths**
- Quick start-up time of trials aids access to US & EU**
- QCTN is one-stop shop to arrange access to**
 - The “best-of-breed” of (pre-)clinical service providers
 - Independent Scientific and Ethics review
 - Independent Biosafety Review for GM-Products

AND

- Desirable destination for overseas clients**



Visit: www.qctn.com.au/members

Remember to visit Brisbane for AusBiotech
October 21-24, 2007

www.ausbiotech2007.com.au



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www.qctn.com.au