



# **Quality: is it just a fairy tale?**

Mario Pennisi, CEO QCTN Inc.

*altogether better*

# Outline

- ❑ **Introduction**
- ❑ **QCTN and its Members**
- ❑ **Regulation and Clinical Trials Processes**
- ❑ **Challenges for the Clinical Trials Industry in Queensland**

# Global Pharmaceutical Sales by Region, 2006 (in billion)

World Audited Market	2006 Sales in US\$	% Global Sales	% Growth year-over-year
North America	289.9	47.7	8
Europe	181.8	29.9	4.8
Japan	56.7	9.3	-0.7
Asia, Africa & Australia	52	8.6	12.9
Latin America	27.5	4.5	12.9

Source: IMS Health

> 15% spent on R&D/Clinical Development

altogether better

# Australia: Active Biotech & Device Industry

<b>BIOTECHNOLOGY</b>	<b>2006</b>
Number of core biotechnology companies (listed and not)	427
Number of listed biotechnology companies	76
Total market cap of listed biotechnology companies	\$15.3 b
Total revenue of listed biotechnology companies	\$3.3 b
<b>R&amp;D 15% ~ 495 million AUD</b>	

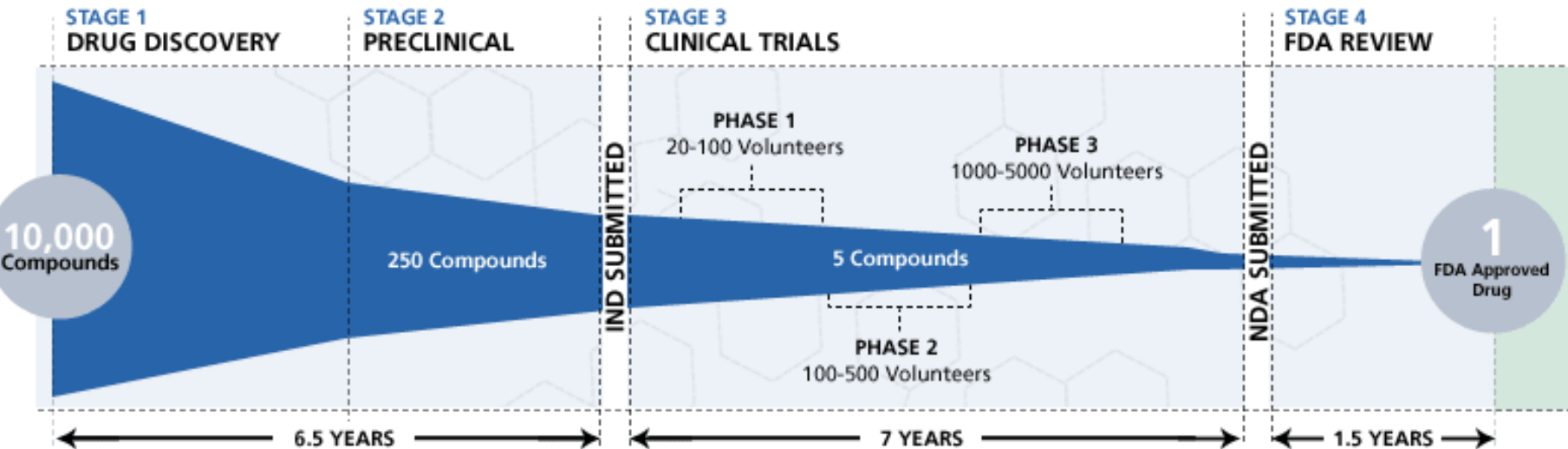
<b>DEVICES</b>	<b>2006</b>
Number of medical devices companies	625
Number of listed devices companies	48
Total market capitalisation	\$11.2 b
Total revenue	\$2.6 b
<b>R&amp;D 15% ~ 390 million AUD</b>	
Total employment across both sectors	12,100

Source:  
2007 BioIndustry  
Review - Australia  
& New Zealand

Melvin Hopper and  
Lyndal Thorburn,  
Innovation  
Dynamics Pty Ltd

Total employment across both sectors	12,100
--------------------------------------	--------

# Drug Development (Leaky) Pipeline



- ❑ In the 10 years to 2000, for the then top 10 Pharmaceutical companies
  - 38% of experimental drugs dropped out in Phase I
  - 60% of remaining candidates dropped out in Phase II
  - 40% of the remaining dropped out in Phase III
  - 23% of those through the clinic failed to be approved by FDA
- ❑ Cost of getting a drug to market >US\$ 1 billion

# Who undertakes Research & Development of new Drugs or Medical Devices?

- ❑ **Pharmaceutical companies**
- ❑ **Biotech companies**
- ❑ **Medical Device companies**

**And**

- ❑ **Life sciences R&D service providers**
  - Public: eg. university, hospital
  - Private: eg. Phase 1 Clinical Research Units, Contract Research Organisations (CROs)
- ❑ **Quality of Services – impacts value of data obtained**
  - Due Diligence costs!

# Survey Phase 1 Unit in Australia\*

**“Australia has established a competitive and professional industry for the conduct of early phase trials to world-class standards with a sustainable growth path”**

## ❑ Revenue

- > AUD 50 Million

## ❑ Business Sources

- 50-70% business from US, Europe, Japan
- 50% repeat business

## ❑ Competitive Advantage

- Current regulatory system (CTN/CTX)
- Quality of work
- Standards of care and medical infrastructure
- Cost effective compared to US/Western Europe

\* Source: Report on a Survey of Australia's Phase 1 Clinical Trials Units, Pharmaceuticals Section, Dept. of Industry, Tourism and Resources, Australian Federal Government, September 2007 *altogether better*

# Example: Q-Pharm Pty Ltd

## Brisbane, Queensland

- Royal Brisbane & Women's Hospital Complex
- Co-located within Queensland Institute of Medical Research

## Specialists in early phase clinical trials

- Inspected by the FDA
- Phase I/II
- Pharmacokinetic and Pharmacodynamic studies
- Proof of Concept studies
- Bio-Equivalence/Bio-Availability



Lab (F Floor)

Clinic (D Floor)

Mervyn Eadie Clinic, Outpatients Clinic

*altogether better*



- ❑ Located at The University of Queensland in Brisbane, Queensland
- ❑ State-of-the-art facilities
- ✓ GLP recognized
- ❑ Member of the Queensland Clinical Trials Network
- ✓ Bio-analytical lab: NATA accreditation/compliance with ISO/IEC standard 17025-1999



Head Office

# Summary

- ❑ **Drug Research & Development is big business**
- ❑ **Many parts of Drug R&D can be outsourced to specialised service providers**
- ❑ **Poor quality impacts value of data**

# Outline

- **Introduction**

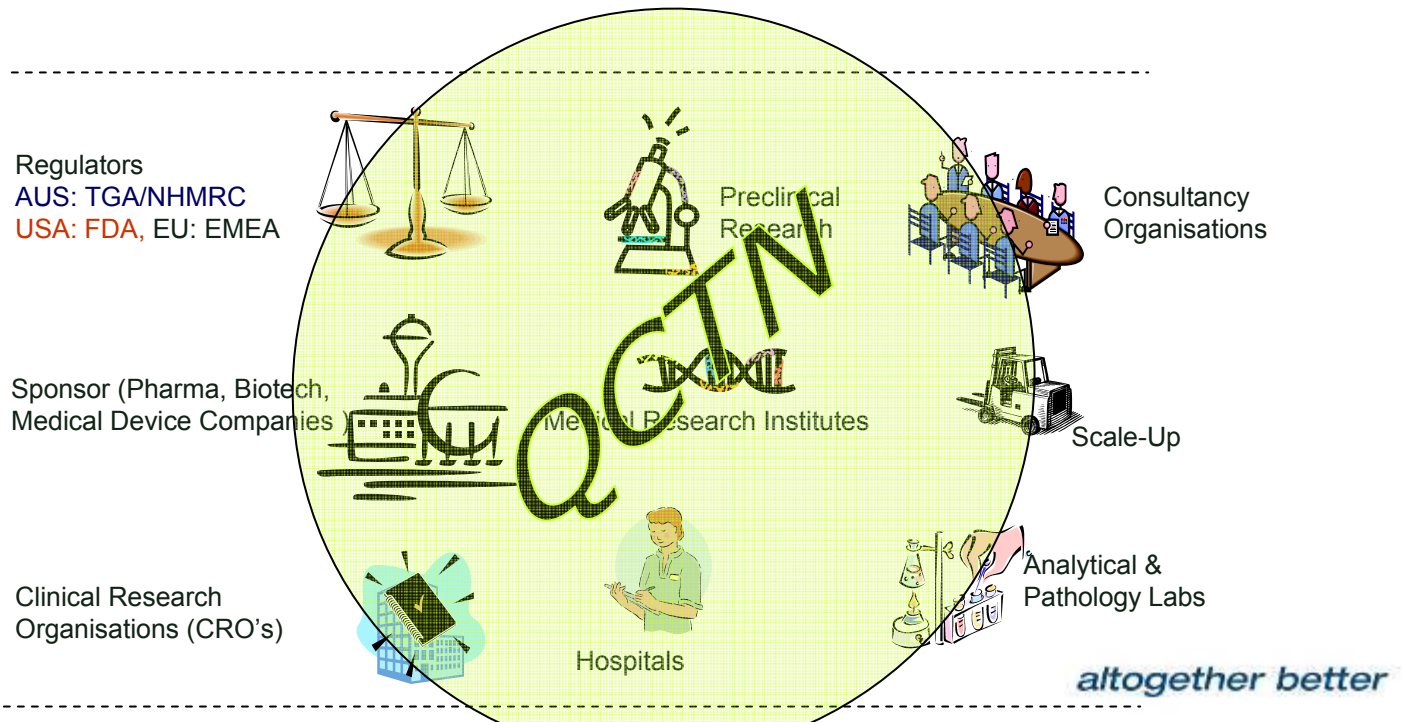
- **QCTN and its Members**

- **Regulation and Clinical Trials Processes**

- **Challenges for the Clinical Trials Industry in Queensland**

# Queensland Clinical Trials Network Inc.

- ❑ QCTN is an independent association of life sciences service providers and hospitals (“umbrella organisation”)
- ❑ Aim: To help organisations undertake preclinical and clinical trial activities in Australia (one-stop shop)



# Clinical Trials Capabilities of QCTN Members

## QCTN Members cover all aspects of drug development

- Clinical Network Services
  - Q-Pharm
  - ERA Consulting
  - TetraQ
  - The Wesley Research Institute
  - Core Research Group
  - QIMR
  - Genomics Research Centre
  - Emphron
  - Symbiosis
- 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.
  - Commercialisation



Please visit:

[www.qctn.com.au/members](http://www.qctn.com.au/members)

altogether better



# QCTN Services

## ❑ **Promotion of QCTN Member Organisations**

- Tradeshows & Conferences, QCTN Missions
- Networking with “networks”

## ❑ **Provision of infrastructure & know-how**

- Independent HREC= IRB and IBC (Biosafety)
- SOS (Staff on Site), Education & Networking

## ❑ **Facilitation of industry events**

- Clinical Research Excellence 2008 Conference (CRX-08), Brisbane, 7-9 August, 2008
- ClubBIO, Gold Coast, 11-12 September, 2008

## ❑ **Alliances with other organisations**

- BARQA
- ACRP
- KHIDI

# Outline

❑ **Introduction**

❑ **QCTN and its Members**

❑ **Regulation and Clinical Trials Processes**

❑ **Challenges for the Clinical Trials Industry in Queensland**

# Australia's "Duty Impliers"

- ❑ **Australian Regulatory Authority for regulating Medicines and Medical Devices is called TGA**
  - **T**herapeutics **G**oods **A**dministration
  
- ❑ **Other important regulatory entities are:**
  - **Ethics:** National Health and Medical Research Council (NHMRC)
  - **Genetically Modified Products:** Office of Gene Technology Regulator (OGTR)
  - **Radiation Products:** The Australian Radiation Protection and Nuclear Safety Agency
  
- ❑ **Australian regulations consistent with international guidelines (ICH)**

# Clinical Trials: The Rules

- ❑ **Good Clinical Practices (GCP)**
- ❑ **Good Laboratory Practices (GLP)**
- ❑ **Good Manufacturing Practices (GMP)**
- ❑ **Good Storage Practices**
- ❑ **Many other rules, guidelines, codes, directives, etc.**

## Essentials of predicate rules like GCP:

- **Rights, safety and well-being of subjects most important**
- **Scientifically and ethically sound studies**
- **Recording and careful handling of all information**
  - Enable verification
  - Evidence to show one is “in control”

# In Control of Clinical Trials: Many Parties, Many Rules

AUS: **TGA**/NHMRC

USA: **FDA**,

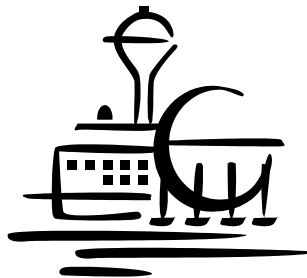
EU: **EMA** + local  
Regulators



**HREC:**  
Human  
Research &  
Ethics  
Committee

**Sponsor**

(Pharma, Biotech,  
Medical Device  
Companies )



Experimental  
Drug/Device

Principal  
Clinical  
Investigator



Patient

Pharmacy



Hospital  
Personnel



Laboratory

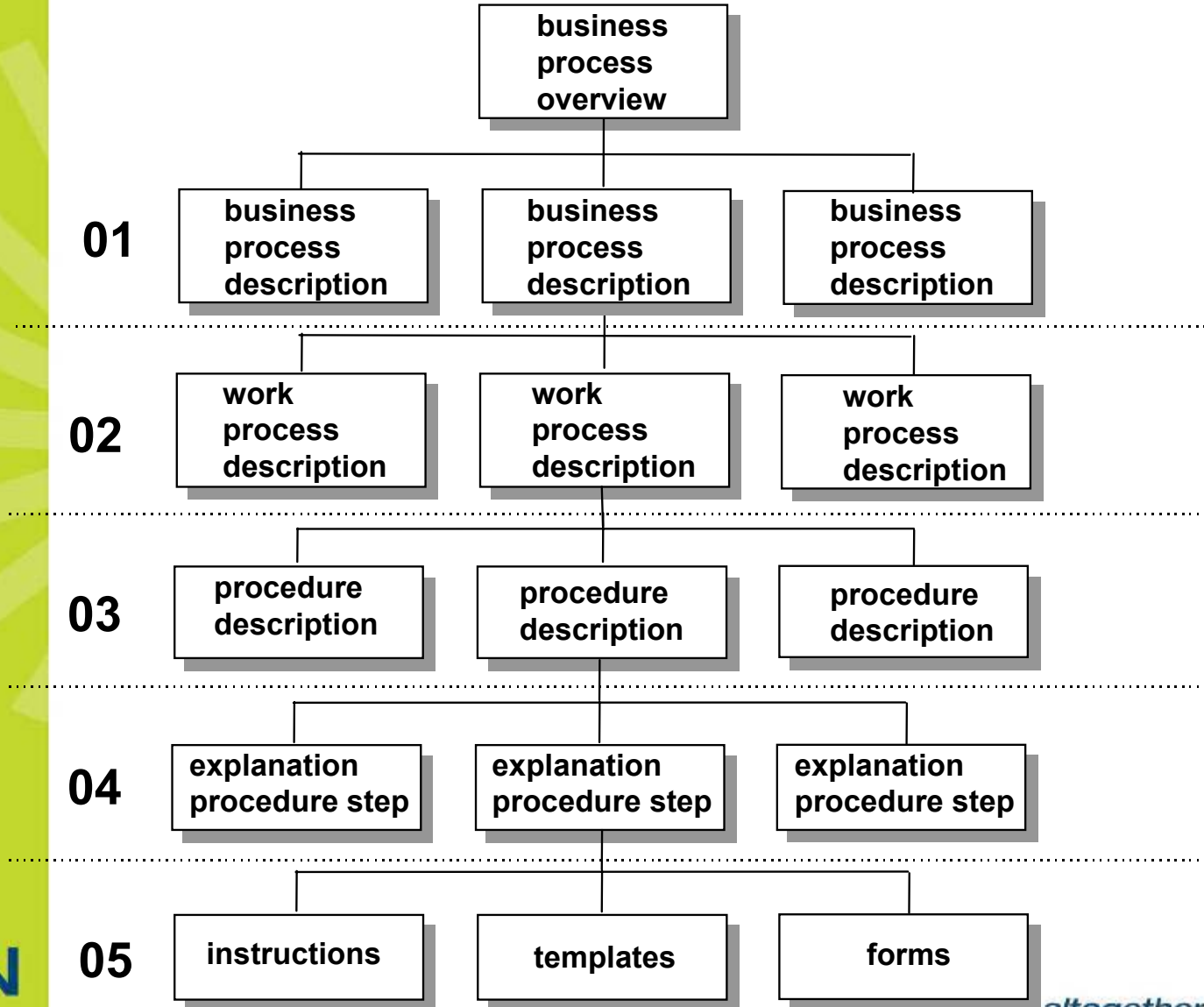


**CRO's** (Contract Research  
Organisations – Support Services )

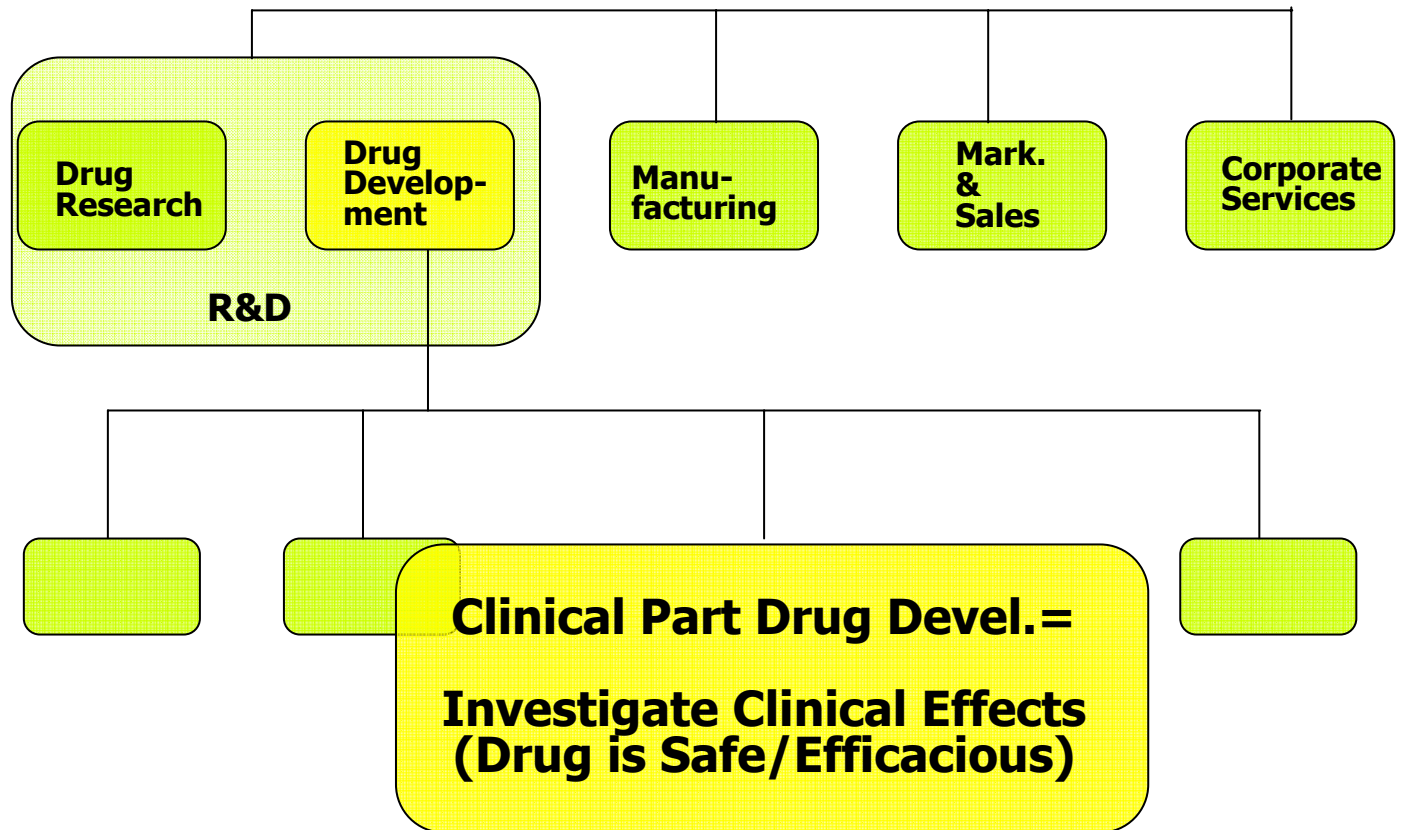


*altogether better*

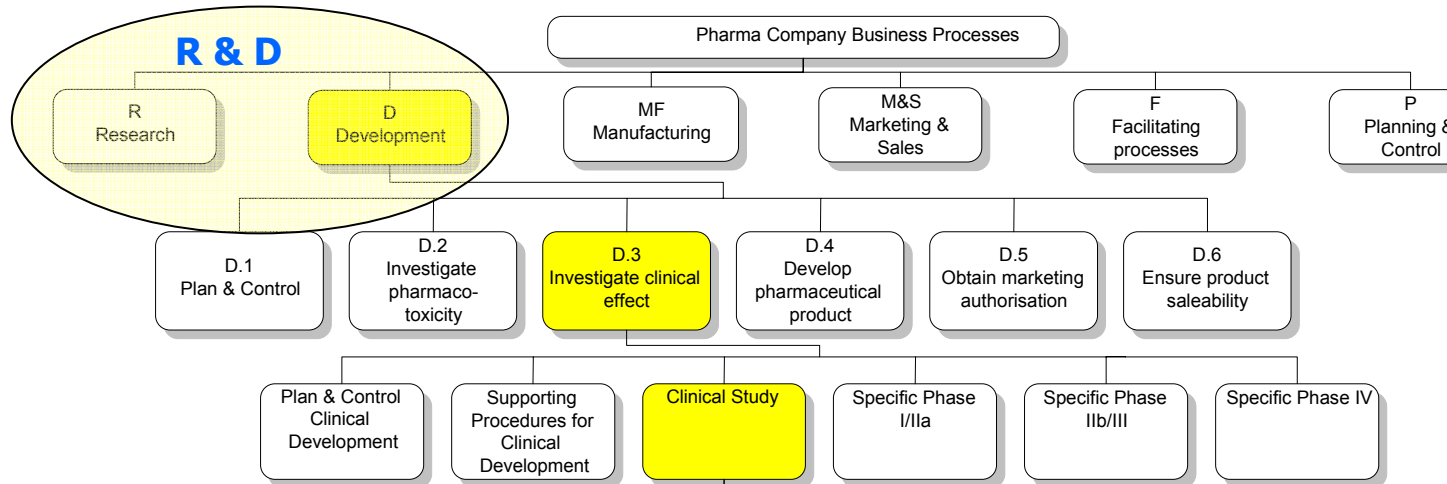
# Typical model for documenting processes



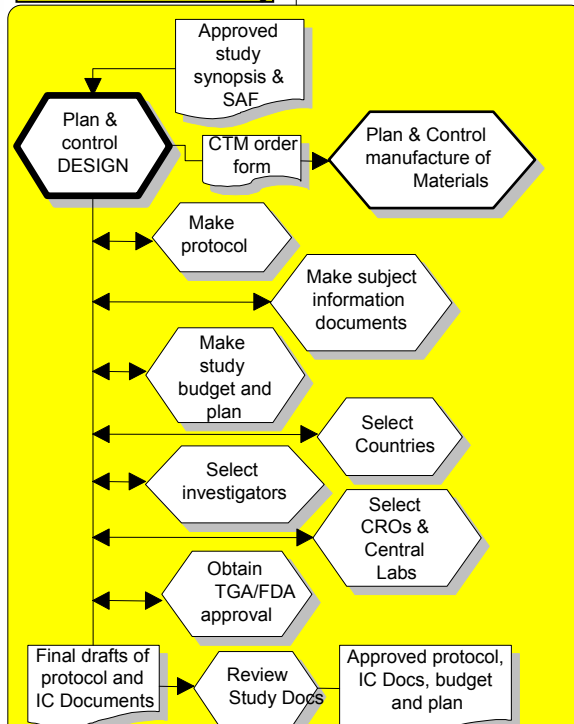
# Process Hierarchy in Drug R&D – 1 of 2



# Complete Process Hierarchy in Drug R&D – 2 of 2



## DESIGN Clinical study



PREPARE clinical study

EXECUTE clinical study

REPORT clinical study



altogether better



# Summary

- ❑ **Drug Research & Development is big business**
- ❑ **Many parts of Drug R&D can be outsourced to specialised service providers**
- ❑ **Poor quality impacts value of data**
- ❑ **Queensland has many R&D service providers, many of whom are members of QCTN**
- ❑ **Clinical Trials are complex, cross-organisation processes which need to meet strict regulatory guidelines**

# Outline

- ❑ **Introduction**
- ❑ **QCTN and its Members**
- ❑ **Regulation and Clinical Trials Processes**
- ❑ **Challenges for the Clinical Trials Industry in Queensland**

# Challenges for the Clinical Trials Industry in Queensland

- ❑ **Craft skills of clinicians not in doubt – good doctors**
- ❑ **Current environment conducive to clinicians undertaking clinical trials but good doctor ≠ good researcher**
- ❑ **Conducting clinical trials requires**
  - Compliance with regulations – most notably GCP
  - Training in research methodology: study design & analysis
  - Biostatistics support (a trial represents a sample of patients)
- ❑ **Failure to have quality systems and qualified researchers in place poses a risk to patients AND to the industry of life sciences R&D service providers**

# Overall Summary

- ❑ **Drug Research & Development is big business**
- ❑ **Many parts of Drug R&D can be outsourced to specialised service providers**
- ❑ **Poor quality impacts value of data**
- ❑ **Queensland has many R&D service providers, many of whom are member of QCTN**
- ❑ **Clinical Trials are complex, cross-organisation processes which need to meet strict regulatory guidelines**
- ❑ **To be commercially viable, one needs to have appropriate quality systems in place whereas non-commercial or inexperienced organisations may not have them in place ⇔ challenge**
- ❑ **A common quality standard for life sciences R&D service providers in Qld needs to be created**

# Fairy Tale about Quality

## ☐ Three Little Pigs

☐ Straw

☐ Stick

☐ Brick



Visit: [www.qctn.com.au/members](http://www.qctn.com.au/members)



*Postal address:*  
PO Box 1307  
Sunnybank Hills QLD 4109

*Office address:*  
Level 3, 88 Jephson Street  
Toowong QLD 4066  
Australia

*Phone:* +61 7 3331 3999  
*Fax:* +61 7 3870 9101

*altogether better*

[www.qctn.com.au](http://www.qctn.com.au)