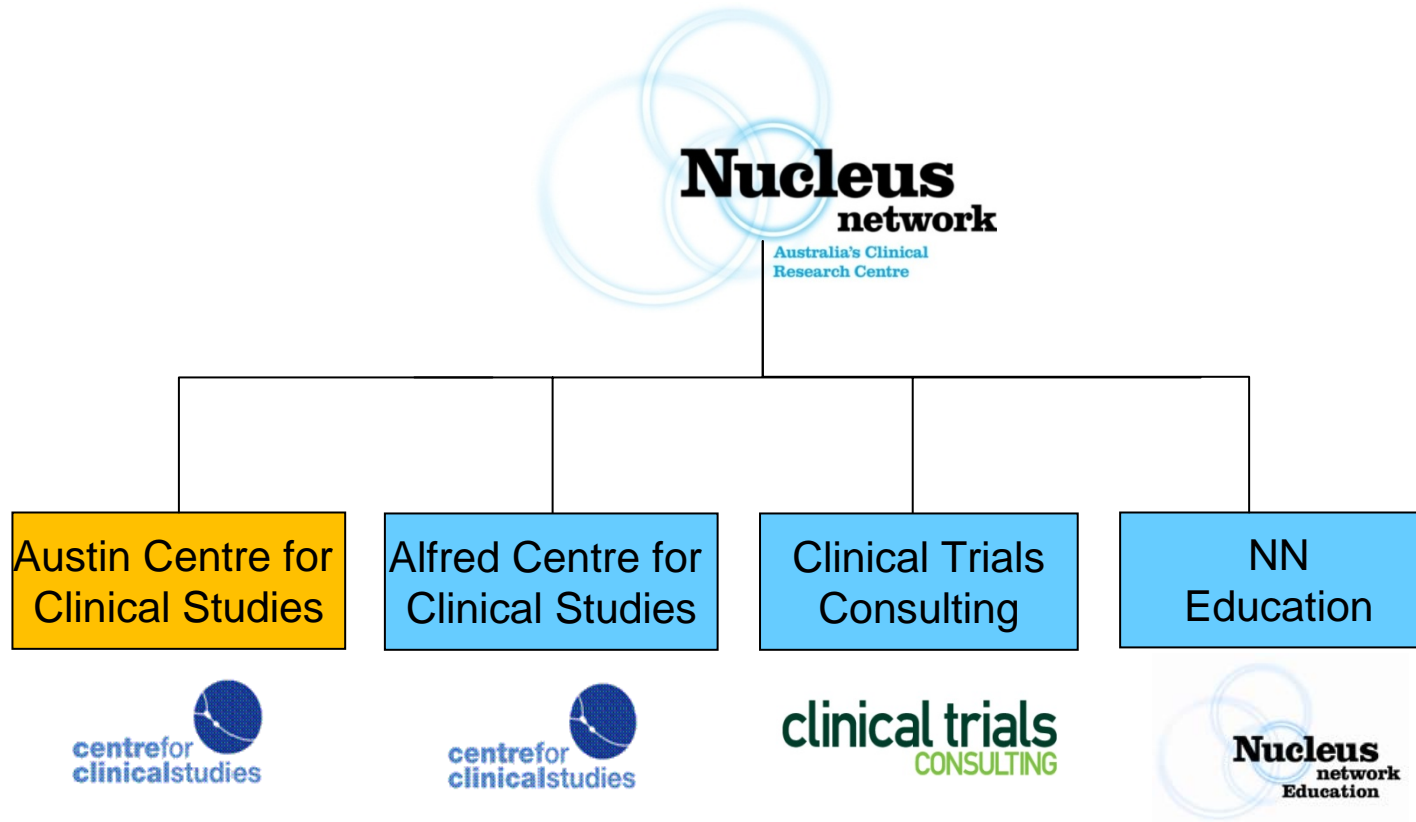


Austrade - *Partnering with Australia*
October 2008

Nucleus Network is an Early Phase Clinical Trial Specialist



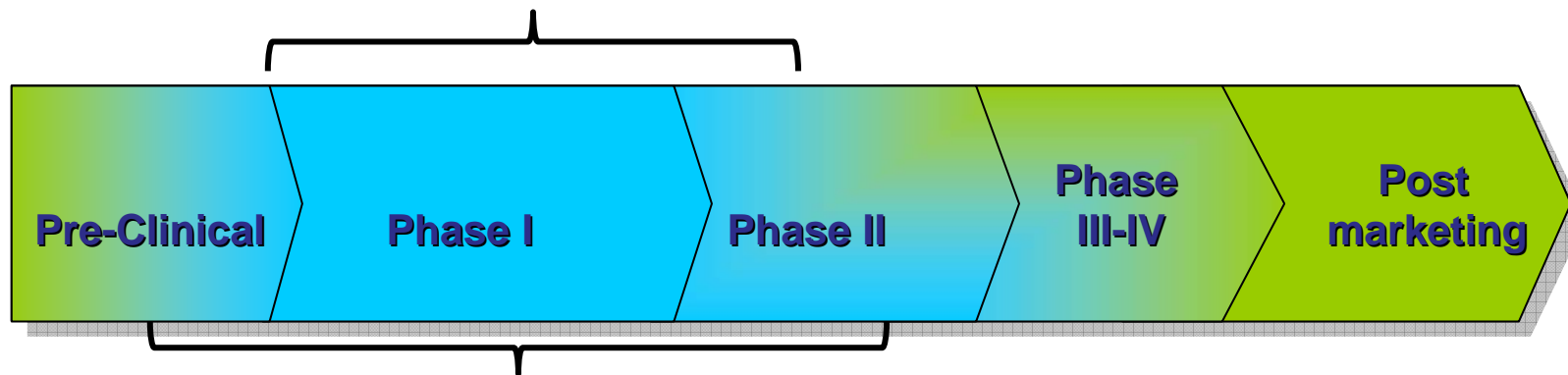
Nucleus Network is a not-for-profit company,
wholly owned by Baker IDI

Nucleus Network Early Phase Focus



Centre for Clinical Studies

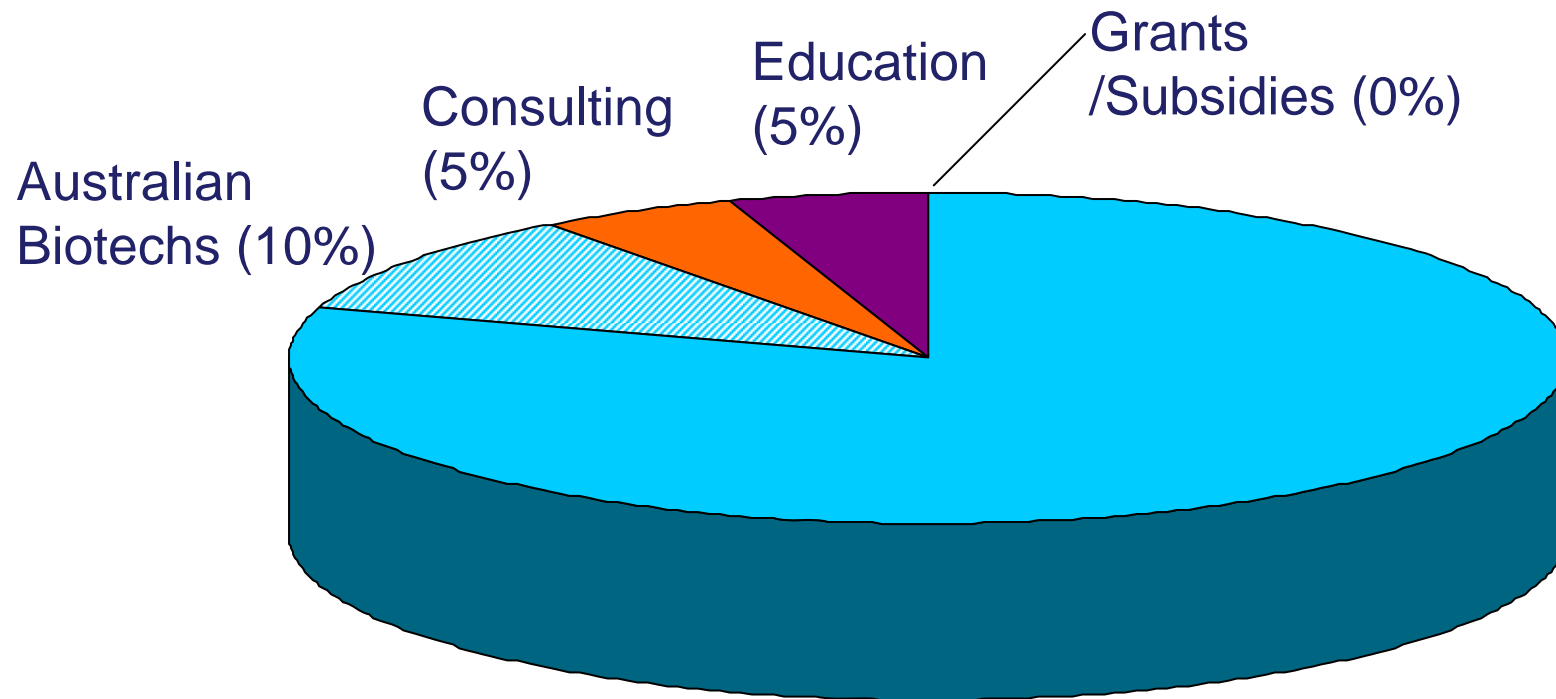
- First-in-Human
- PK / PD
- Food effect



Clinical Trial Consulting

- Pre-clinical gap analysis
- IB preparation
- Protocol writing

Nucleus Network - International Focus



7 of top 10 Pharma
2 of top 5 Biotech

International Customers
(80%)



The Centres for Clinical Studies



- **Centre for Clinical Studies AMREP**
 - World-class 30 bed inpatient facility for healthy volunteers and specialised patient groups
 - Operational since 2004
- **Austin Centre for Clinical Studies**
 - World-class 16 bed inpatient facility for healthy volunteers and specialised patient groups
 - Operational since 2008

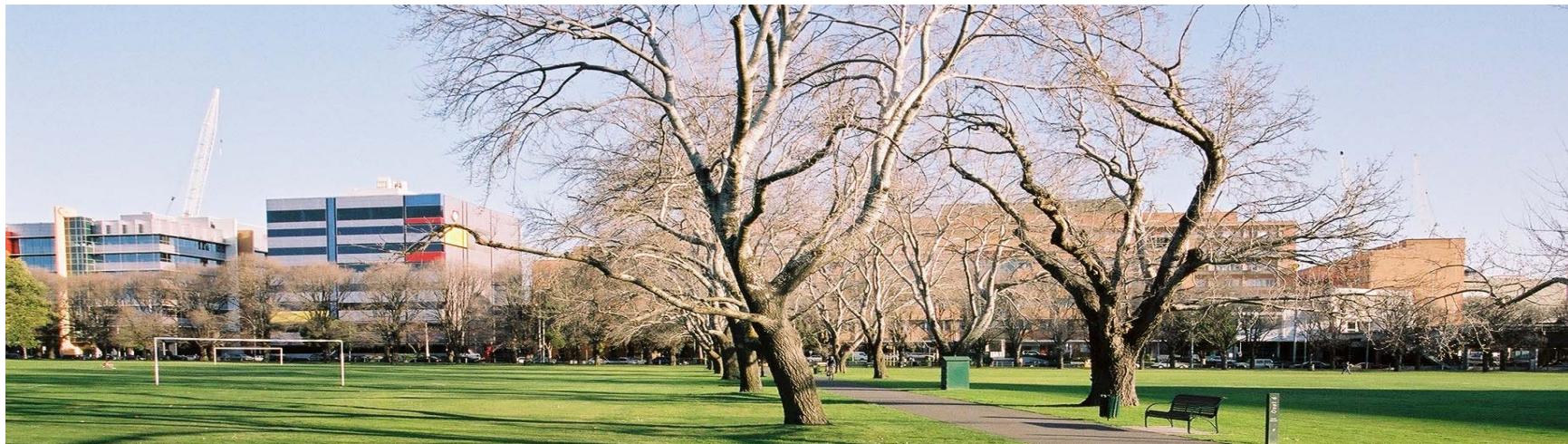
A Unique Operating Model

- **Very close links to major tertiary teaching hospitals**
 - Specialist Principle Investigators for most therapeutic areas
- **Very close links to major Medical Research Institutes**
 - Advanced biomarker and other PD end-points
 - Development of customised assays
- **Pro-active project management to accelerate projects**
 - Local sponsorship
 - No 'IND' filing required
 - 'just-in-time' final formulation

Alfred Medical Research Education Precinct (AMREP)



- Alfred:
 - National Trauma Research Institute
 - Heart/Lung Transplant
 - Respiratory Disease/Asthma
 - Oncology
 - Psychiatry
- Monash:
 - Medicine
 - Surgery
 - Pathology & Immunology
 - Epidemiology & Preventive Medicine
 - Australian Centre for Blood Disorders
- Baker IDI – Cardiovascular/Diabetes
- Burnet – Infectious Diseases
- Home to Nucleus Network:
 - Centre for Clinical Studies
 - Clinical Trials Consulting
 - Nucleus Network Education



Austin Health



➤ Ludwig Institute for Cancer Research - LICR



➤ National Stroke Research Institute – NSRI

➤ Florey Institute subsidiary



➤ Brain Research Institute - BRI



➤ Institute for Breathing and Sleep - IBAS



➤ Epilepsy Research Centre - ERC



➤ Parent – Infant Research Institute - PIRI



➤ Australian Centre for Post-traumatic Mental Health - ACPTMH



➤ Austin Hospital Medical Research Foundation - AHMRF

Austin specialties include:

- Oncology
- Neurology
- Respiratory
- Aged care
- Spinal and head injuries
- Mental health

University of Melbourne:

- Medicine
- Surgery
- Psychiatry
- Physiotherapy

Home to Nucleus Network

- Austin Centre for Clinical Studies
- Clinical Trials Consulting

Recent External Audits - CCS



Date	Sponsor / Agency	Type and Duration of Audit	Subsequent Work Placed at NN
October 2008	US biotech	2 day vendor qualification	Yes
June 2008	FDA	5 day study audit	Nil 483s
April 2008	US Biotech	½ day vendor qualification	Yes
Feb 2008	Multinational Pharma	1 day vendor qualification	Yes
October 2007	Top 10 Pharma	2 day study specific	Yes
October 2007	Top 10 Pharma	2 day study specific	Yes
September 2007	Australian Pharma	1 day vendor qualification	Yes
April 2007	Top 10 Pharma	2 day vendor qualification	Yes
March 2007	US Biotech	2 day vendor qualification	Yes
February 2007	Australian Biotech	1 day vendor qualification	Yes
November 2006	US Biotech	2 day vendor qualification	Yes
September 2006	Top 10 Pharma	3 day vendor qualification	Yes
August 2006	Top 10 Pharma	2 day vendor qualification	Yes

Clinical trials completed or in progress



- Asthma Phase I
- Cardiovascular (Hypertension, Chronic Heart Failure), Phase I-IV
- Crohn's Disease Phase I
- Coronary Artery Bypass Graft Phase II-III
- Cirrhosis (Portal Hypertension) Phase IIa
- Complimentary Medicine Phase II-III
- Dermatology Phase I, III
- Diabetes Phase I-IV
- Dyslipidaemia Phase IIa, IV
- ENT Phase I, III
- Hep C Phase I
- Medical Devices Phase I-II
- Menopause Phase I-III
- Oncology Phase I-II
- Onychomycosis Phase I
- Pain Phase I
- Psoriasis Phase I
- Renal Disease Phase III-IV
- Rheumatology Phase I
- Transdermal Application Phase I
- Vaccine Studies Phase II-III
- Food Interaction Phase I
- Drug Interaction Phase I
- Single Ascending Dose Phase I
- Multiple Ascending Dose Phase I
- Absolute Bioavailability Phase I
- Japanese vs Caucasian Metabolism Phase I





2008 Governor of Victoria Export Awards - Winners

- ✦ **AGRIBUSINESS AWARD**
Longwarry Food Park
- ✦ **ARTS & ENTERTAINMENT AWARD**
Torus Games
- ✦ **EDUCATION AND TRAINING AWARD**
Deakin University
- ✦ **EMERGING EXPORTER AWARD**
Nucleus Network
- ✦ **INFORMATION & COMMUNICATIONS TECHNOLOGY AWARD**
OSR International
- ✦ **LARGE ADVANCED MANUFACTURER AWARD**
Redflex Traffic Systems Pty Ltd
- ✦ **LARGE SERVICES AWARD**
WorleyParsons Services Pty Ltd
- ✦ **REGIONAL EXPORTER AWARD**
Mobius Software
- ✦ **SMALL TO MEDIUM SERVICES AWARD**
Rhine Ruhr
- ✦ **SMALL TO MEDIUM MANUFACTURER AWARD**
Advanced Polymer Technology Australasia Pty Ltd
- ✦ **SMALL BUSINESS AWARD**
Global EARS Limited
- ✦ **SPORTS, EVENTS & TOURISM AWARD**
Zoos Victoria
- ✦ **VICTORIAN EXPORT AWARD FOR INNOVATION EXCELLENCE**
Nucleus Network
- ✦ **VICTORIAN EXPORTER OF THE YEAR AWARD**
Advanced Polymer Technology Australasia Pty Ltd

2008 Governor of Victoria Export Awards
A big round of applause for Export Success



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Benefits of Specialist Capabilities – Case Study I - Formulation



Situation:

- Large US biotech wanting to establish proof of concept for an inhalation product before finalising product formulation
- Limited availability of manufacture (time / cost)
- Special patient population (CF)

NN Solution:

- Final stage formulation and batch release performed by NN / Alfred to GMP requirements
- Recruitment of CF patients via specialist PI and NN direct recruitment

Customer outcome:

- Proof of principle study completed to GCP / GMP standards
- Accelerated formulation selection (12 month time saving)
- Significant direct and indirect cost reduction
- Focussed IND to be filed to achieve rapid approval

Benefits of Specialist Capabilities – Case Study II - Japanese



Situation:

- Multi-national Pharma needing to rapidly conduct a Japanese / caucasian bridging study
- Targeted at regulatory approval
- Special patient population (Japanese with documented ancestry)

NN Solution:

- Targeted recruitment of Japanese population in Melbourne based on multi study experience
- Japanese trained and speaking Principal Investigator
- Subject care tailored for cultural requirements to ensure retention of subjects to completion

Customer outcome:

- Rapid ethical approval
- Rapid recruitment, study conduct and database closure

Benefits of Specialist Capabilities – Case Study III - Biomarkers



Situation:

- Large US biotech wanting to conduct a first in man biological study with study specific biomarker assays
- Unknown stability of samples for biomarker

NN Solution:

- Rapid approval through experienced phase I (including first-in-man biologicals) – utilising external toxicology & immunology review in parallel to ethics review
- Local conduct of cytokine stimulation assay under CO₂ incubation based on sponsor trained and validated methodology

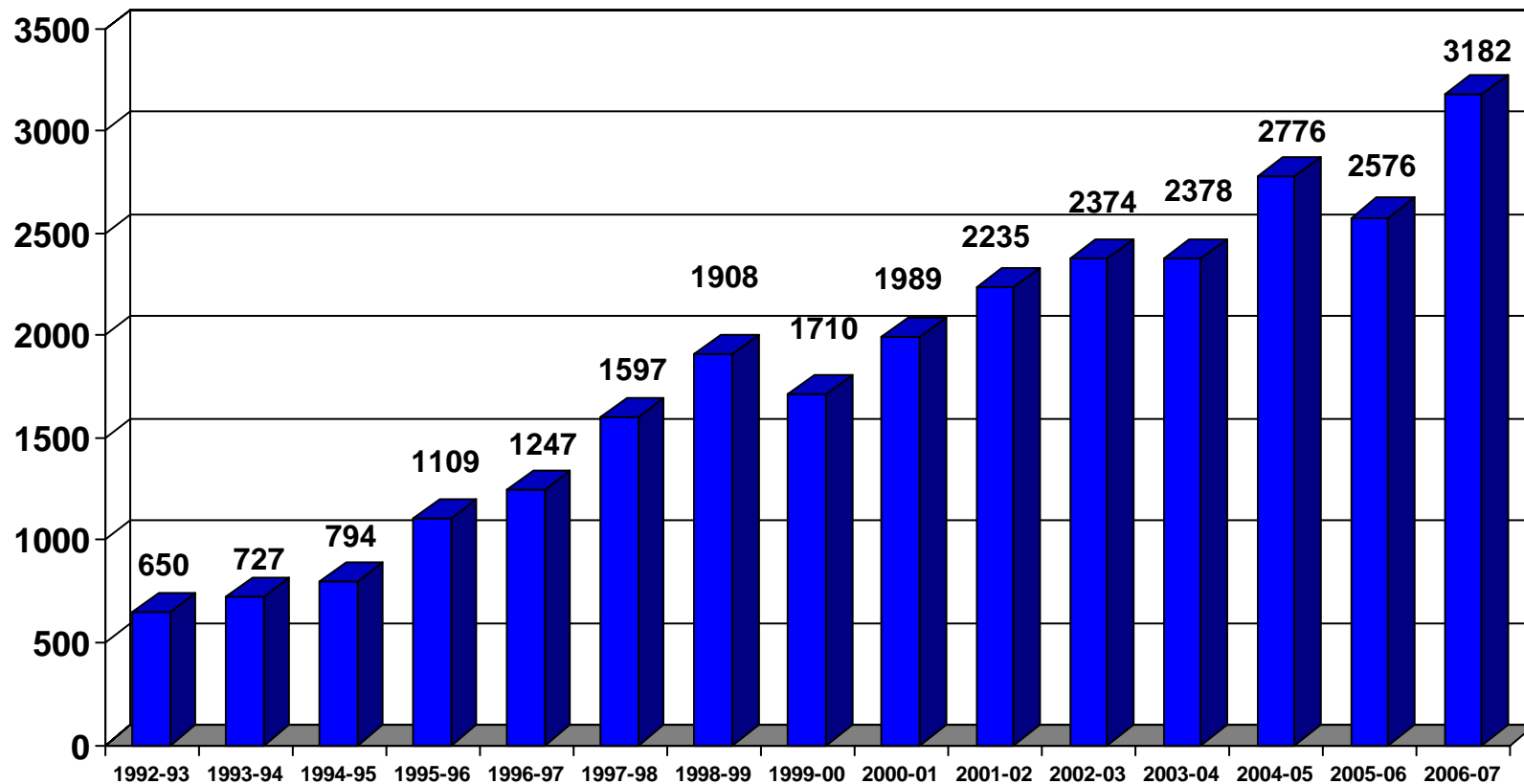
Customer outcome:

- Rapid study start up
- Rapid dose escalation decisions through fast data turn around
- Accelerated development plan through subsequent IND filing including initial patient data and cytokine stimulation results

Clinical Trial Applications in Australia

- **Clinical Trial Notification (CTN)**– Ethics committee approves the study and TGA gets notified. Agency does not evaluate the research on the product therefore there is no Agency approval
- **Clinical Trial eXemption (CTX)**– Ethics committee approves the study but the TGA reviews a dossier of information consisting of CMC and preclinical information (safety and quality). TGA approves a study to start under the specified usage criteria applied for

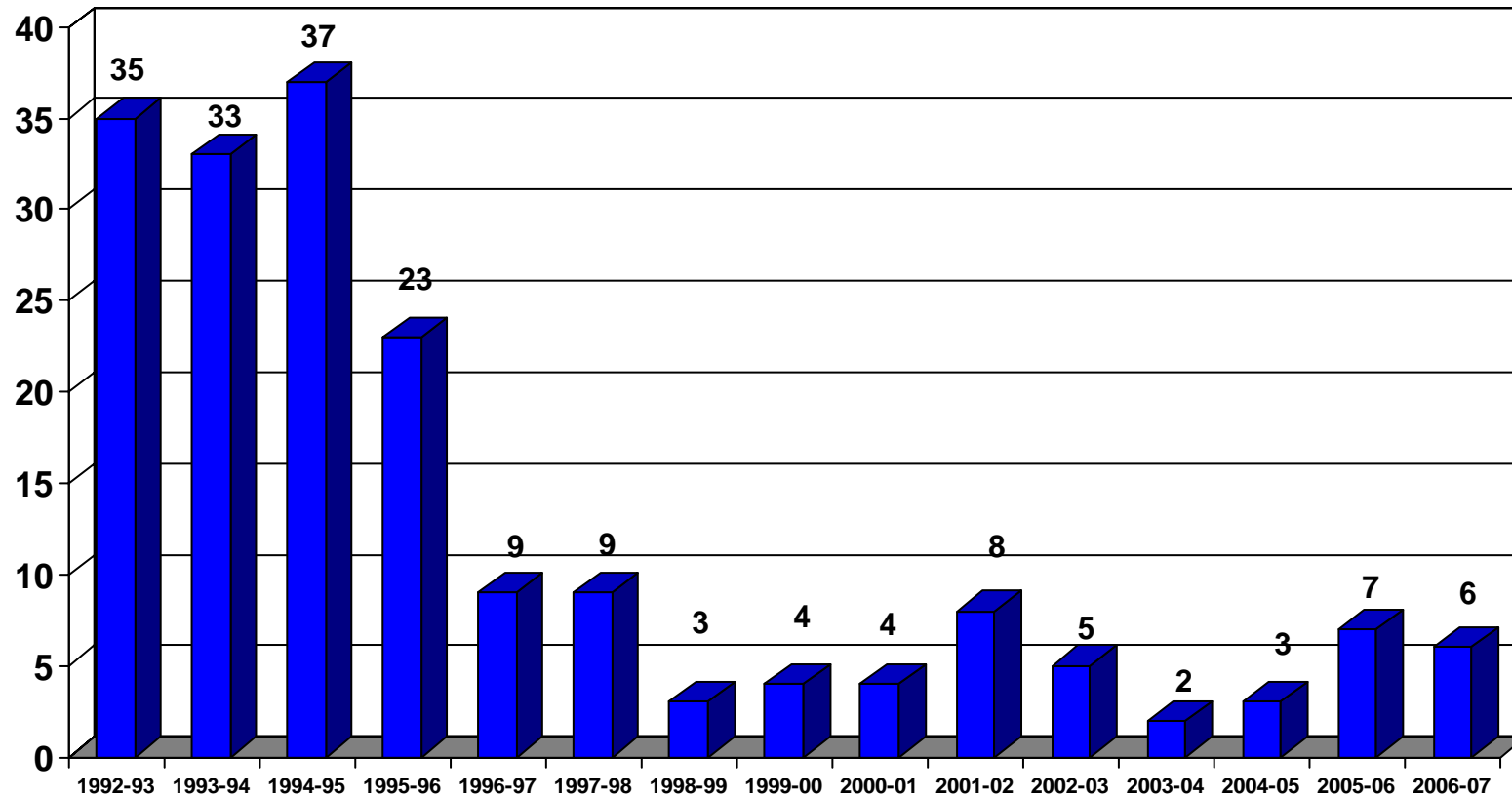
Clinical Trials in Australia - CTN Applications



99.8% of trial sites are approved under CTN



Clinical Trials in Australia - CTX Applications



Nucleus Network is an expert on the Australian Regulatory Process

Process	CTN (Clinical Trial Notification)	CTX (Clinical Trial Exemption)
TGA Review	Not required	√
Human Research Ethics Approval	√	√
Agency Timelines	7-14 days	30 days or 50 days
Fees	\$A240 (\$US188)	\$A15,300 (\$US11,964)
% per year	99	1

CTX similar to IND