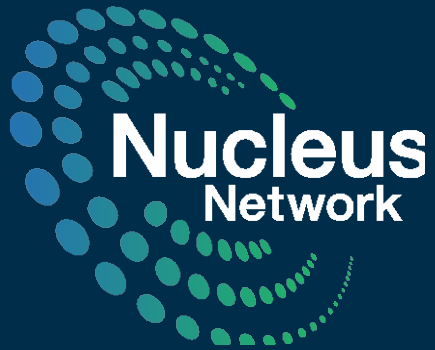
Welcome to

Nucleus Network



About Us

Nucleus Network: Key Facts And Figures

MOST EXPERIENCED

first-in-human specialists and the largest early phase clinical trials site in Australia

15+

years in operation

700+

Phase 1 clinical trials completed, with 70 Phase 1 clinical trials conducted per annum

INSPECTIONS

By FDA and EMA and previously ANVISA certified

50%

of all the trials we conduct annually are true first-in-human

Quality Standards & Audit History

FDA & EMA COMPLIANCE

1

Australian Data is accepted by Regulatory Submission by FDA & EMA

2

Australian Phase I Data regularly used to support IND Applications for U.S. Phase II Clinical Trials

3

FDA & EMA Inspected Phase I Facilities

ANVISA Certified

Typical Customers coming to Australia

Spanning biotechnology, pharmaceutical and CROs from all over the world

THEIR LOCATIONS

Global clients from North America, Europe and Asia, including China and Taiwan

80%

of Nucleus Network client base are biotechnology companies

20+

Chinese based Biotechnology companies have collaborated with Nucleus Network

Australia’s Phase I Therapeutic Experience

Value-added partners capable of addressing the unique challenges of early clinical development

Direct access to hospitals and world class research institutes

Strong relationships with hospital-based principal investigators, individual researchers and medical schools

Therapeutic expertise and established recruitment channels for patient studies and First-in-Human adaptive protocol designs

Anesthesiology

Cardiology

Dermatology

Endocrinology

Gastroenterology

Infectious Disease

Neurology

Nephrology

Ophthalmology

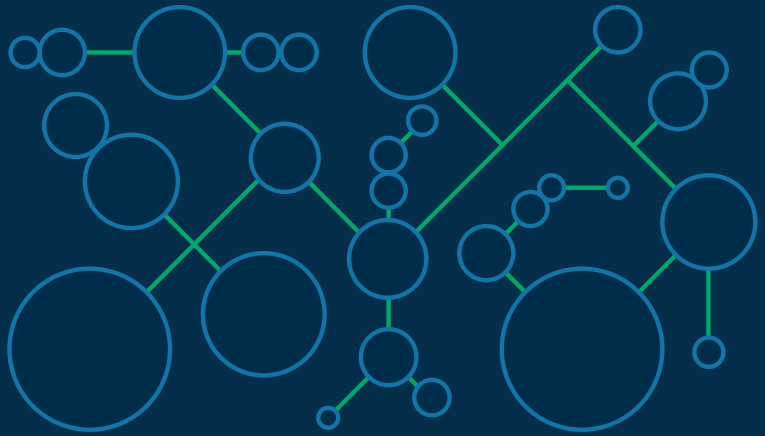
Oncology

Respiratory

Rheumatology

Types of trials being conducted in Australia

Extensive experience in evaluating small molecules and biologics in both healthy volunteer and patient populations



Bioequivalence/ bioavailability

—

Biosimilars

—

Challenge Studies

—

Cytochromes P450 genotypes

—

Drug interaction

—

Ethno-pharmacology

—

First-in-human

Food interaction

—

Multiple ascending dose

—

Proof of concept

—

Single ascending dose

—

TQTC monitoring

—

Vaccines

Access To Hospitals & Research Precincts for Specialist PD Biomarkers

Melbourne Phase I facility (80 beds) co-located with The Alfred Hospital (800 bed tertiary teaching hospital)

—

Brisbane Phase I facility (60 beds) co-located with The Royal Brisbane and Women's Hospital (900 bed tertiary teaching hospital)

—

Nucleus Network has access to a population of over 7.5 million across both cities

Allergy
(gluten challenge, nasal challenge, skin prick testing)

—

Cardiology
(Cardiac Stress Test, Transthoracic Echocardiogram)

—

Imaging
(CT, Dexa, MRI, PET, Ultrasound, X-ray)

—

Neuroscience
(Lumbar punctures, EEG, Cogstate)

—

Pain Assessment
(Cold Pressor Testing, Von Frey & Thermostimulatory

—

Respiratory

(BAL, Spirometry including FEV1 and FVC)

Financial Incentives

FAVORABLE EXCHANGE RATES, R&D TAX SCHEME

1

Current USD exchange rate
Trading at USD 70-72c to AUD $1
Expected to remain stable

Source: Commonwealth Bank US dollar forecast

2

Refunds of up to USD 45c in every USD $1 spent for eligible companies

Source: Frost & Sullivan Independent Research report

Australian Regulatory Process

Clinical Trial Notification (CTN) Scheme

- Regulation of clinical trials in Australia is based around the CTN Scheme
- TGA is the Australian Government regulator of medicines and medical devices
- The primary review aspect of the CTN process is assigned to the Human Research Ethics Committees (HREC)
- Following HREC approval the CTN is submitted to TGA for notification only

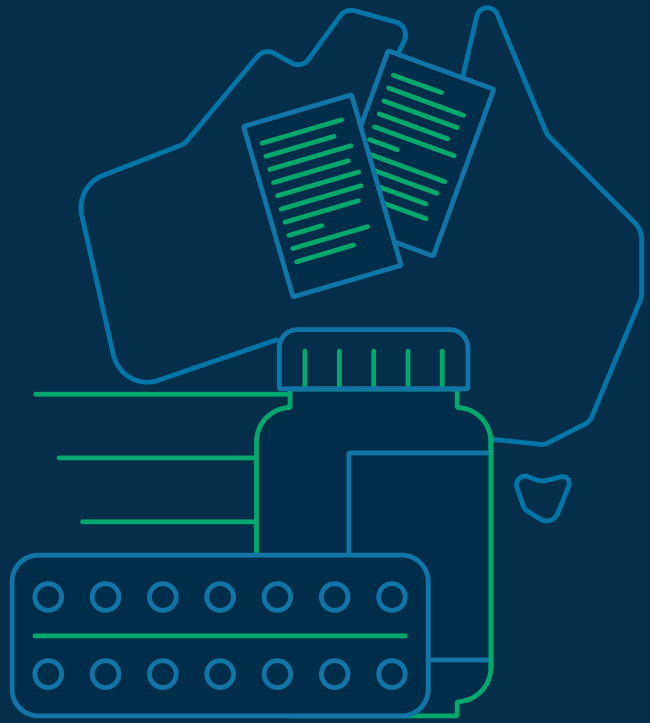
Human Research Ethics Committee (HREC)

- All clinical trials in Australia require the approval of an HREC
- Essentially, reviewer of the scientific and ethical aspects of a clinical trial
- HREC is responsible for reviewing the trial protocol, the investigator's brochure and patient information and consent form.

Australia’s Regulatory System

The benefits of working in Australia

- Studies approved within 4—5 weeks of IRB submission, including HRECs review
- No IND or IMP required
- First-in-patient studies can be conducted within 6—8 weeks
- Australian data is accepted by regulatory submission by FDA & EMA
- Data regularly used to support IND applications for U.S. Phase 2 clinical trials
- Limited CMC package and non-GMP material accepted



Thank You

Contact:
Jeffery Wong (Business Development Manager)
j.wong@nucleusnetwork.com.au

—

nucleusnetwork.com.au