



INSTITUTION PROFILE

DEDICATED TO DISCOVERY

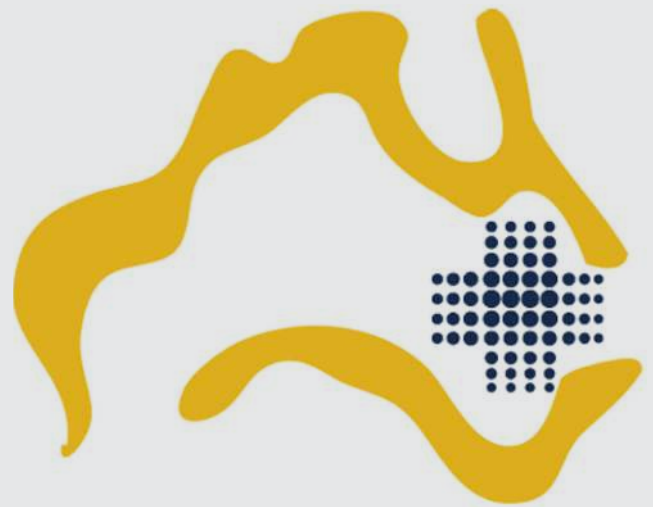
COMMITTED TO CARE

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I AusTrials Background

AusTrials is a private, multi-site organisation dedicated to pharmaceutical research. First established in 2009, AusTrials is a leading private clinical research organisation in Australia. Conducting trials from Phases Ib (including first-in-humans) to Phase IV in the areas of general medicine including gastroenterology, respiratory medicine, endocrinology, dermatology, cardiology, mental health as well as healthy participant studies. The AusTrials network has recently expanded and now covers Australia's Eastern seaboard with sites in Melbourne, Sydney and two in Brisbane.



Sites are strategically co-located within medical facilities allowing access to multiple healthcare services and 3rd party vendors.

Why Choose AusTrials?

- Long standing reputation of conducting research and delivering quality data since 2009
- Access to representative samples of the surrounding community
- Strategic location of sites in medical precincts within easily accessible populous areas.
- Modern facilities and infrastructure tailored for:
 - In-patient study visits, and multipurpose areas for infusions and longer-period treatments, PK sampling
 - Preparation, handling and storage of IP, and other investigational materials.
- Quick communications turnaround for feasibilities, CTRA and budget creation, start-up, RGO and ethics submissions
- A fast and efficient study start-up process
- Multipurpose areas for mass vaccination studies, infusions PK sampling and longer-period treatments
- Database of 6,800+ potential participants

Institution Contacts:

| | |
|---------------------------------|---|
| Institution name | Data Health Australia Pty Ltd |
| Trading name | AusTrials |
| ABN | 89 623 449 945 |
| Central Hub and Billing Address | Suite 302, Level 3, Westside Private Hospital, 32 Morrow Street, Taringa QLD 4068 |
| Telephone: | +61 7 3278 5255 |
| Fax: | +61 7 3278 5266 |
| Email: | info@austrials.com.au |
| Working hours: | 08:00am – 04:00pm Monday to Friday |

Personnel

| MAIN POINTS OF CONTACT | CONTACT DETAILS |
|--|--|
| Dr Munro Neville Managing Director | E: munro.neville@austrials.com.au M: +61 449 580 483 T: +61 7 3278 5255 |
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| Jenifer Smith Quality Officer | E: jenifer.smith@austrials.com.au T: +61 7 3278 5255 |
| Maddison Harvey Ethics & Study Start-Up Coordinator | E: maddison.harvey@austrials.com.au T: +61 7 3278 5255 |
| Marco Rauseo MD Client Success Manager Study Feasibilities | E: marco.rauseo@austrials.com.au M: +61 406 244 340 T: +61 7 3278 5255 |

CVs available upon request.

AusTrials Experience

| | |
|---------------------------|--|
| Therapeutic areas | <ul style="list-style-type: none">• General Medicine• Vaccinations• Gastroenterology• Endocrinology• Respiratory medicine• Immunology and allergies• Dermatology• Men and women’s health• Weight management• Chronic pain |
| Trial phases | Ib to IV |
| Patient Population | 5 years of age and older |
| Number of studies | Over 165 studies |

Latest Recruitment Highlights

- High recruiter in phases I to III covid vaccine studies - 2021-23
- Top recruiter in knee osteoarthritis study – 2023
- Enrolment of 140% of initial target in meningococcal vaccine study – 2021

Record of Studies

Over 165 studies conducted in a wide range of general medicine areas: cardiology, endocrinology, gastroenterology, respiratory medicine, acute respiratory illnesses, dermatology, vaccinations and prophylactic treatments, women’s health, men’s health, mental health, musculoskeletal conditions, among others.

Investigators

Investigator team is composed of eight Investigators experienced in all study phases within a wide range of medical conditions. They have a deep understanding of the conduct of clinical trials as well as principles of Good Clinical Practice (GCP), informed consent, and case report forms.

Study Coordinators

Study Coordinators are fully trained and experienced Registered Nurses, and have completed training for IATA, Shipment of Dangerous Goods, and GCP and proficient in all the leading eCRF and randomisation platforms.

In-house dedicated recruitment team

Highly qualified staff, with life sciences training dedicated to the elaboration of recruitment strategies, pre-screening of potential participants and retention strategies. This includes coordination and management of social media and website advertisement.

Additionally, the team has the capacity to generate recruitment reports on a regular basis and provide relevant updates to sponsors and CROs quickly and efficiently.

Ethics Submissions

AusTrials has the capacity to be the lead site for study submission. Our Ethics team has extensive experience with Bellberry Human Research Committee. However, applications can be submitted to the sponsor's preferred committee.

Initial submissions have a turnaround time of 4-6 weeks. Subsequent submissions have a turnaround time of 2-4 weeks.

RGO

AusTrials has a Management Committee which functions as a Research Governance Committee (RGO). AusTrials RGO/Management Committee meets **regularly** with a standard agenda and minutes recorded. However, continual governance occurs in-between meetings to ensure a prompt start-up process. RGO review occurs simultaneously with HREC review.

Information for Sponsors and CROs

Source Documentation and Storage

Paper based source documents are used. After COV, documents are stored in compliance with the Guidelines of The National Health and Medical Research Council (NHMRC) Australian Code for the Responsible Conduct of Research, generally for 15 years or longer, as appropriate. Documents are stored off site at a secure archival facility, for secure archiving and are accessible when required. Documents will be destroyed by high temperature incineration at the archival facility at completion of the required archiving period.

SOPs

AusTrials has a comprehensive library of Standard Operating Procedures on

- General Administration
- Clinical Procedures
- Infection Control
- Facility Management
- Subject Management
- Trial Management

AusTrials SOPs can be shared upon request during site visits. Please note that these are intellectual property of AusTrials and should not be shared with third parties without permission.

Contracts and Indemnity

AusTrials work with the Medicines Australia approved templates for CTRA and Indemnity contracts for expedited processing.

Contracts can be in place within 2-3 weeks.

Site Monitoring

Space for on-site monitoring visits can be accommodated on all sites. In order to ensure space, supporting staff and participant source availability, please request your visit up to two weeks in advance. Investigators will be available during monitoring visit if requested.

Documentation Storage

All paper-based documentation including ISF is stored behind locked doors within the facility accessible only by AusTrials staff members. Blinded and unblinded staff members will have access to different documentation, so we suggest limiting correspondence with necessary staff members in order to maintain blinding and confidentiality.

Destruction of IP and Ancillary Supplies

Kit verification and certificate of destruction AusTrials can conduct this process for a fee.

Source Documents

We develop our own source material tailored to the requirements of the protocol. All source material is paper based and filed in participants charts. AusTrials does not keep electronic source records.

Third Party Vendors

AusTrials has established relationships with third party vendors for the following services: radiology (including interventions), nutrition and exercise counselling, local laboratories, and pharmacy. Other specialists are included in study delivery when needed, such as ophthalmology, gynaecology, etc

Prior Audits

Last not-for-cause audit conducted in 2023 – No significant findings.



AusTrials Sites

Our sites are designed to accommodate multiple participants at a time and maximize the number of visits. We strongly believe that the participant is the first priority, and pride ourselves in having a personalised approach. Consultation rooms provide a comfortable atmosphere guaranteeing a seamless participant experience.

Examination rooms

All our examination rooms are private and equipped with:

- Examination beds
- Blood chairs
- Sphygmomanometers
- Thermometers (Oral, tympanic, non-contact infrared)
- Weight scales
- Stadiometers
- Pulse oximeters
- 12-lead ECG
- Distress alarms

NOTE: All sites are equipped with emergency resuscitation trolleys and associated procedures all medical staff are trained in.

Laboratories and Pharmacy Rooms

Lab rooms and Drug rooms.

Ample lab room with locked cupboards for unblinded and IP documentation.

| Lab Rooms | Pharmacy Rooms |
|---|--|
| <ul style="list-style-type: none">• Dedicated space for sample processing, packaging, and shipment.• Temperature controlled centrifuges• 2-8°C Fridge and back up• -20°C Freezer and backup• -80°C Freezer• Contaminated waste disposal• Aliquoting equipment | <ul style="list-style-type: none">• Dedicated space for IP preparation• Ample shelves for IP storage• 15-25° controlled ambient storage <p>*Room is locked and accessible only by delegated staff.</p> |

Data Access: Commercially sensitive and blinded information is stored in locked cupboards that can be accessed only by unblinded or blinded staff members as appropriate.

Temperature Monitoring: Fridges, freezers and drug rooms are temperature controlled and monitored 24/7 using a cloud based, remote access system with live alerts on temperature excursions. Temperature logs are systematically downloaded and electronically stored. These can be shared on an agreed frequency.

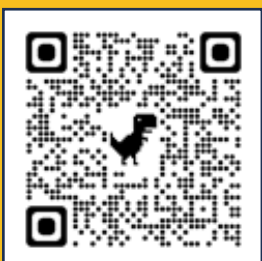
AusTrials Taringa – AusTrials Hub

| Main Points of Contact | Contact Details |
|------------------------|---|
| Address: | Suite 302, Level 3, Westside Private Hospital Building. 32 Morrow St, Taringa QLD 4068 Australia |
| Telephone: | +61 7 3278 5255 |
| Fax: | +61 7 3278 5266 |
| Email: | taringa@austrials.com.au |
| Transportation: | 25-minute drive from Brisbane Airport 15-minute drive from Brisbane CBD Directly next to Taringa train station Free parking accessible through Moggill Road. |

Facilities:

- 3 Consultation rooms, including a GMO compliant room.
- Lab Room
- Pharmacy Room
- On site ophthalmology, respiratory medicine, gastroenterology and other specialities
- On site radiology with plain X-rays, CT, MRI and interventional radiology

| Main Points of Contact | Contact Details |
|--|--|
| Dianna Ang Hub Manager | E: dianna.ang@austrials.com.au T: +61 7 3278 5255 |
| Mariel Bahan Site Supervisor | E: mariel.bahan@austrials.com.au T: +61 7 3278 5255 |
| Dr Florence Tiong Principal Investigator | E: florence.tiong@austrials.com.au T: +61 7 3278 5255 |



Virtual Tour of the Taringa Facility

AusTrials St Leonards

| Main Points of Contact | Contact Details |
|------------------------|--|
| Address: | Suite 404, Tower A, North SHore Health Hub, 7 Westbourne Street, St Leonards, Sydney NSW 2065 |
| Telephone: | (02) 8313 1599 |
| Fax: | (02) 8376 5090 |
| Email: | stleonards@austrials.com.au |
| Transportation: | 20-minute drive from Sydney Airport 15-minute drive from Sydney CBD 10-minute walk from St Leonards Train Station Direct access via multiple bus routes |

Facilities:

- 3 Consultation rooms, including a GMO compliant room.
- Multipurpose area for longer stay visits (PK sampling, IV infusions, etc.) or mass vaccinations.
- Lab room
- Pharmacy room
- Meeting / training room
- Ample CRA monitoring stations
- On site radiology with plain X-rays, CT, MRI and interventional radiology
- On site pathology and pharmacy
- Walking distance from the Royal North Shore Hospital

| St Leonards Points of Contact | Contact Details |
|---|---|
| Shelley Westgarth-Nugent Regional Manager | E: shelley.westgarthnugent@austrials.com.au T: +61 406 244 019 |
| Dr Munro Neville Principal Investigator | E: munro.neville@austrials.com.au T: +61 449 580 483 |
| Megan Gleeson Operations Director | E: megan.gleeson@austrials.com.au T: +61 406 308 314 |

AusTrials Sunshine

| Main Points of Contact | Contact Details |
|------------------------|---|
| Address: | Level 5, Sunshine Private Hospital, 145 -147 Furlong Rd, St Albans VIC 3021 |
| Telephone: | +61 3 9215 0799 |
| Fax: | +61 3 9215 0798 |
| Email: | sunshine@austrials.com.au |
| Transportation: | 15-minute drive from Melbourne Airport 29-minute drive from Melbourne CBD 5-minute walk from Ginifer Train Station. Car park available on-site |

Facilities:

- 3 Consultation rooms, including a GMO compliant room.
- Multipurpose area for longer stay visits (PK sampling, IV infusions, etc.).
- Lab room
- Pharmacy room
- Meeting / training room
- Ample CRA monitoring stations
- On site radiology with plain X-rays, CT, MRI and interventional radiology
- On site cardiology, respiratory medicine, gynaecology and other specialties

| Sunshine Points of Contact | Contact Details |
|--|---|
| Shelley Westgarth-Nugent Regional Manager | E: shelley.westgarthnugent@austrials.com.au T: +61 3 9125 0799 |
| Associate Professor Roy Rasalam Principal Investigator | E: roy.rasalam@austrials.com.au T: +61 3 9125 0799 |

AusTrials Wellers Hill

| Main Points of Contact | Contact Details |
|------------------------|--|
| Address: | Suite 204, Level 2, Brisbane Health Connect Building. 51 Orford Street, Wellers Hill QLD 4121 |
| Telephone: | +61 7 3517 0520 |
| Fax: | +61 7 3278 5266 |
| Email: | wellershill@austrials.com.au |
| Transportation: | 20-minute drive from Brisbane Airport 15-minute drive from Brisbane CBD Car park on-site |

Facilities:

- 2 Consultation rooms.
- Ample lab room with locked cupboards for unblinded and IP documentation.
- Lab room
- Pharmacy room
- Co-located with a busy medical centre

| Wellers Hill Points of Contact | Contact Details |
|--|--|
| Jillian Burdak Site Supervisor | E: jillian.burdak@austrials.com.au T: +61 7 3517 0520 |
| Dr Ferdinandus de Looze Principal Investigator | E: fred.delooze@austrials.com.au T: +61 7 3517 0520 |



Virtual Tour of the
Wellers Hill Facility



Aus Trials