

Clinical Trials in Australia – Choosing your partners

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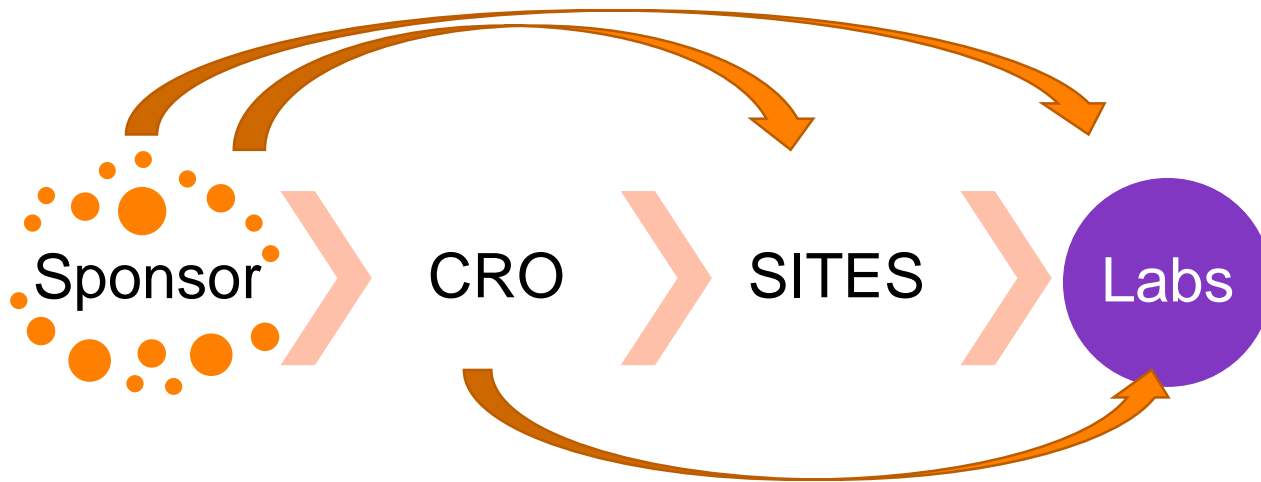
Clinical trials environment

- Australia has a vibrant clinical trials sector with a reputation globally for high quality outcomes
- Australia has more than 50 clinical trial networks offering Phase I – IV clinical trials.
- Multinational and local Clinical research organisations (CRO's) operate with local offices in Australia
- Compliance with Good Clinical Practice (GCP) guidelines means results from Australian trials are regularly used to support submissions to international regulators including the United States' Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Key considerations in Australia

- Time zone difference and response times (CRO needs to have local offices)
- We are used to operating globally (follow international guidelines and recommendations)
- Regulatory processes and governance
- Terminology and acronyms
- Testing may slightly differ (e.g BUN/Urea) – but we will work with you for required outcomes
- Logistics for Multi-site studies nationwide

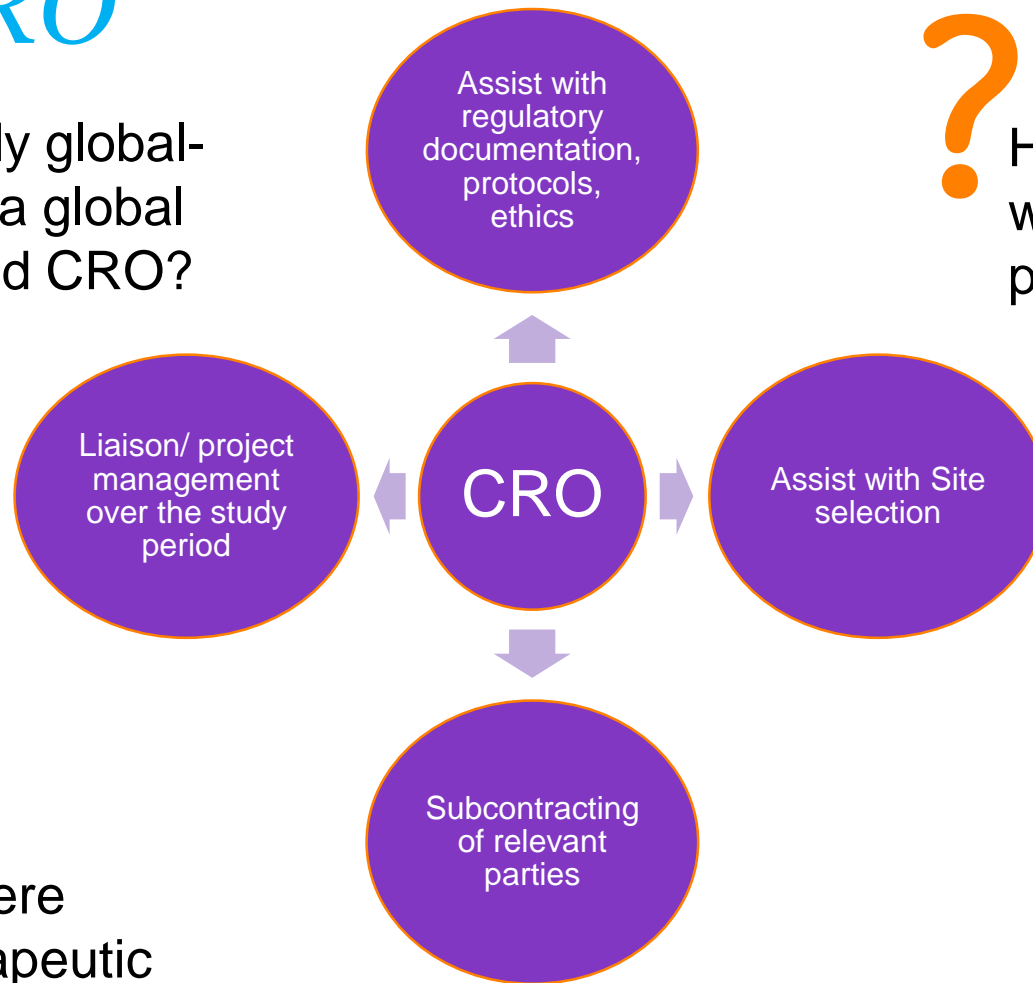
Clinical trials landscape



Services you can expect from your CRO

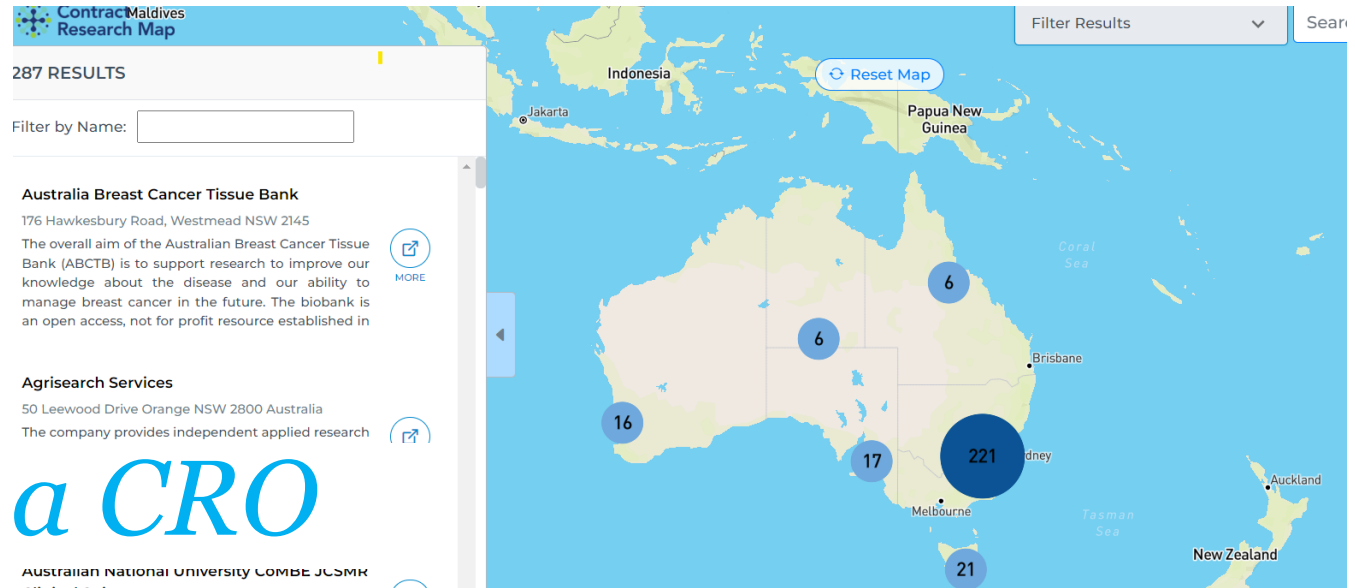
? Is my study global- do I need a global or localised CRO?

? How involved do I want to be in the process?



? Is there therapeutic expertise I need

<https://www.contractresearchmap.com/places/australia>



Finding a CRO

Australian National University COMBE JCSMR

Good Clinical Practice NETWORK
REGULATIONS CRO LIST CLINICAL TRIALS

Contract Research Organizations in Australia in alphabetical order

Alliance Pharma

Alliance Pharma is a global CRO specializing in GLP and non-GLP bioanalytical services, drug metabolism/pharmacokinetic (DMPK) and CMC analytical and materials science services (GMP) for preclinical, clinical, and CMC testing. [View full profile](#)

[View locations](#)

Anatomise Biostats Ltd.

We assist biotechnology, medical device and pharmaceutical start-ups and SMEs to refine and fast-track their research goals through efficient study design, SAPs and protocol development and adaptation, and careful statistical analysis of study endpoint... [View full profile](#)

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Australian Healthcare Solutions

At Australian Healthcare Solutions, we believe in medical technology that changes lives for the better. Australian Healthcare Solutions was founded from the desire to assist companies achieve their vision of delivering credible, safe and cost-effect... [View full profile](#)

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Avance Clinical

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<https://ichgcp.net/cro-list/country/australia>

AUSTRALIAN Clinicallabs | Specialised Trials

Types of sites

<https://www.australianclinicaltrials.gov.au/clinical-trial-sites>

The screenshot shows the 'Australian clinical trial sites' page on the Australian Clinical Trials website. The page includes a navigation menu with 'Industry and sponsors' highlighted. A search bar contains the text 'Industry and sponsors / Australian clinical trial sites'. Below the search bar, there are buttons for 'Search for a Clinical Trial' and 'Register your clinical trial site'. The main content area is titled 'Australian clinical trial sites' and contains the following text: 'Find an Australian clinical trial site. Below are a list of Australian clinical trials sites, including their capacity and capability. You can also select up to 3 sites to compare information about sites.' There are two search filters: 'Search by site' with an input field, and 'State' with a 'Select All' link and checkboxes for ACT, NSW, NT, QLD, SA, TAS, VIC, and WA. There are also four checkboxes for 'Conducting Phase I trials?', 'Conducting Phase II trials?', 'Conducting Phase III trials', and 'Conducting Phase IV trials', each with 'Yes' and 'No' options. At the bottom, there are two dropdown menus for 'Clinical Trial expertise' and 'Dedicated clinical trial unit', both showing 'Anasthaesia and pain', 'Cardiology', and 'Dermatology' as options.

Phase 1

Phase 2-4

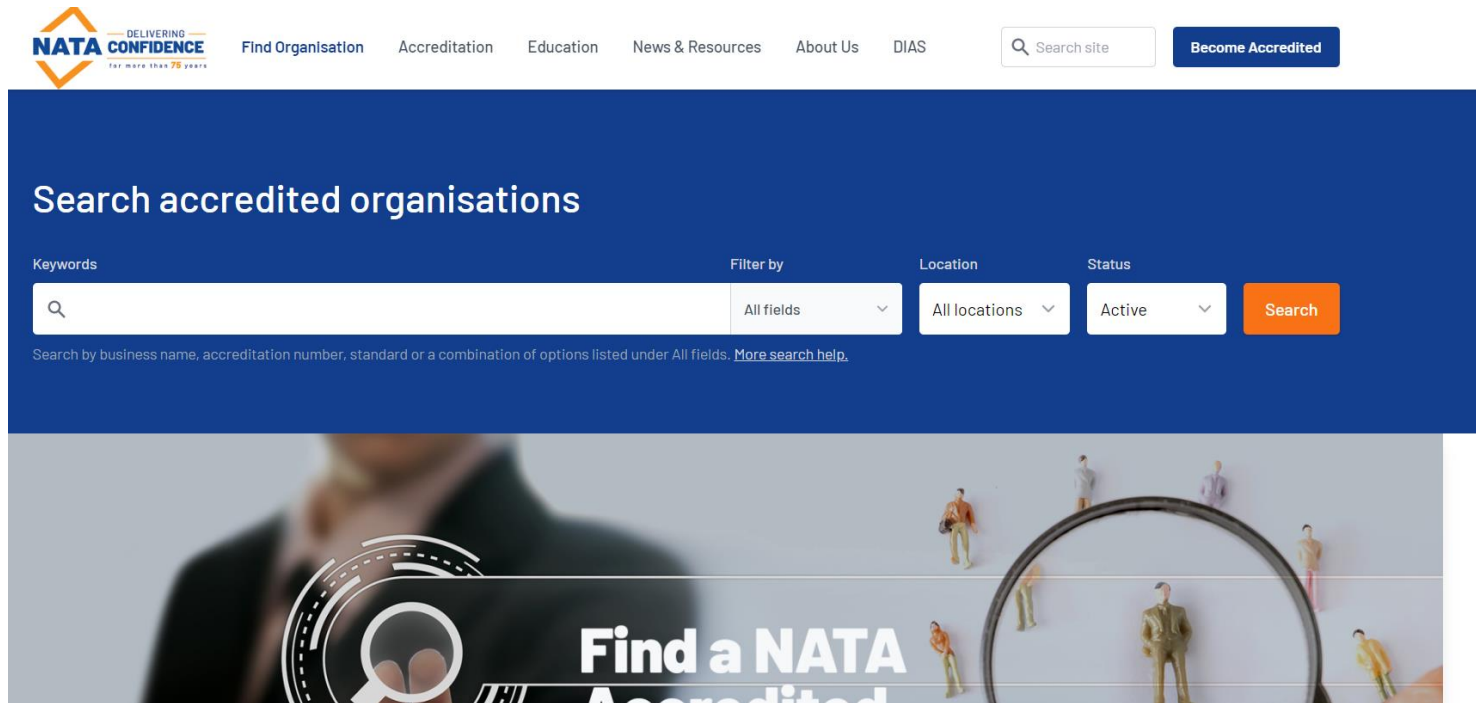
GP clinics/Dr networks

Hospital Sites

The main role is to host trials and provide clinical staff for the conduct of trials on site. Recruiting, treating and monitoring patients in trials on behalf of other sponsors

Pathology, PK, PD, specialist labs- accreditation

<https://nata.com.au/find-organisation/>



The screenshot shows the NATA website's search interface. At the top left is the NATA logo with the tagline 'DELIVERING CONFIDENCE FOR MORE THAN 75 YEARS'. The navigation menu includes 'Find Organisation', 'Accreditation', 'Education', 'News & Resources', 'About Us', and 'DIAS'. A search bar with a magnifying glass icon and the text 'Search site' is present, along with a blue 'Become Accredited' button.

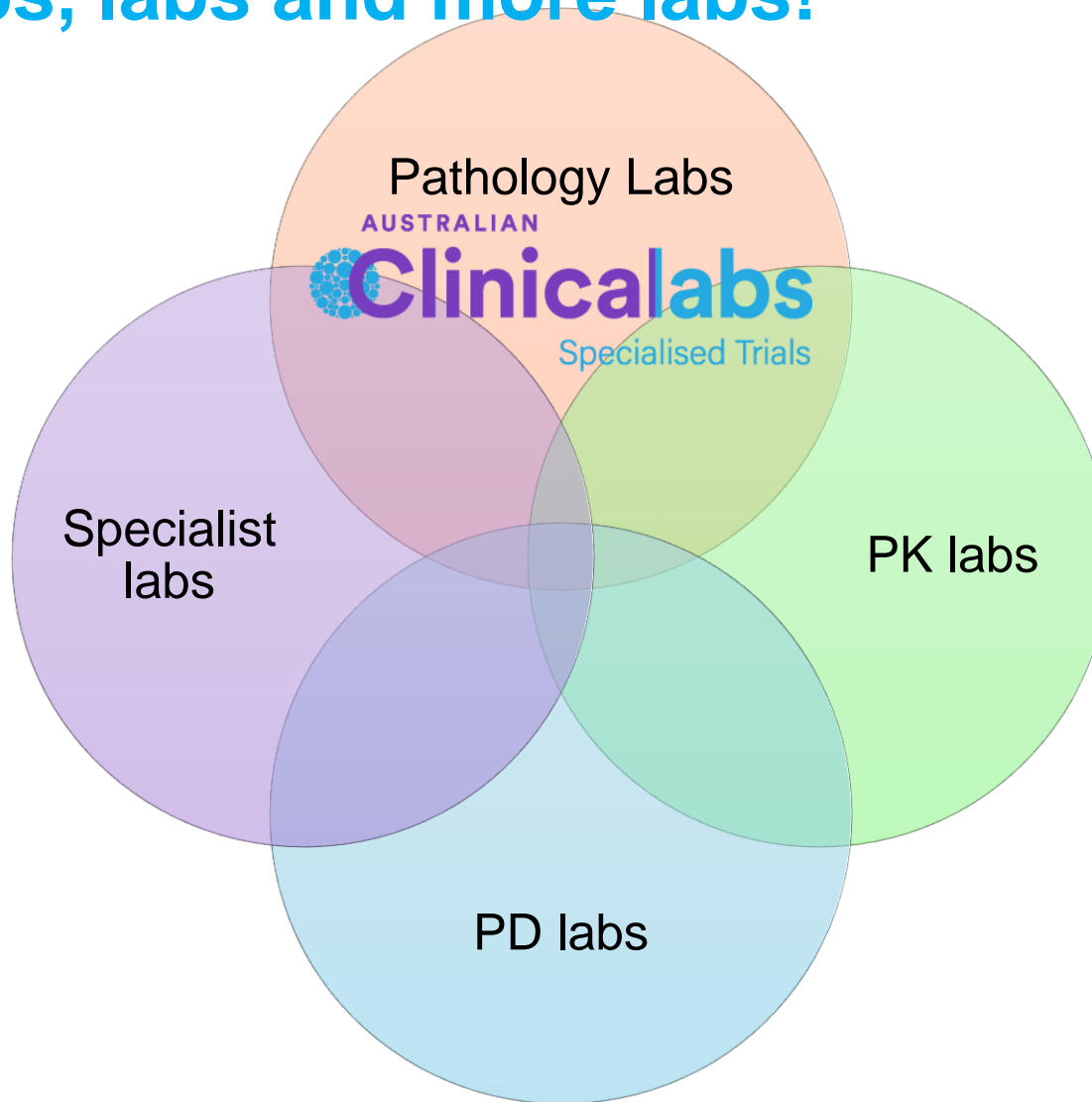
Search accredited organisations

Keywords Filter by Location Status

Search by business name, accreditation number, standard or a combination of options listed under All fields. [More search help.](#)

Find a NATA Accredited

Labs, labs and more labs!



Pharmacokinetics
Pharmacodynamics,
Safety bloods
Screening tests
Biomarkers and
cytokines
Genetic testing
Histology

Virtual Central Lab



Required items provided to each site

ACL's specialised trials project team does internal study setup and prepares customised request forms for all sites.



Samples are transported to the nearest ACL local laboratory most of which have unified national reference ranges— there are ~50 around the country to ensure speed of sample analysis. Study specific reference ranges available.

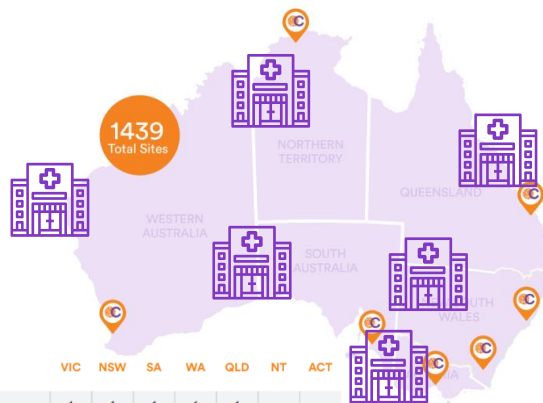


Data delivered to each site via secure web portal or app

ACL's specialised trials project team monitors study progress, respective results delivered to a results portal to each site and ACL delivers single consolidated data extracts to sponsors CRO's or data management teams regardless of the site locations



One
National Unified Pathology System, linking all labs to one information system




Teletrials



Where are you patients?

<https://australianteletrialprogram.com.au/>

Australian Teletrial Program
Access to clinical trials, closer to home



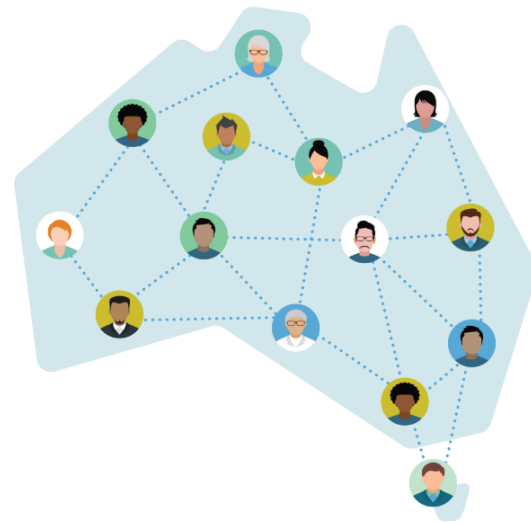
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Vision

The Australian Teletrial Program will improve access to, and participation in, clinical trials for rural, regional and remote Australians.

Teletrials is a proven model and uses telehealth to connect regional and rural clinical trial site clusters.

[Learn More](#)



Contact us for any questions



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Web

www.specialisedtrials.com.au

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