

Smarter Full Service Clinical Trial Partner

Your High Quality, Cost Effective Partner in Australasia for Personalised Clinical Research and Regulatory Affairs. Delivering Clinical Trial Management supported by a strong track record of integrity and reliability.

Pharmaceutical Solutions is proud to promote the quality of Clinical Research and Regulatory Affairs in the Australasia region and of our contribution to improving people's health and well being. We achieve this through the provision of personalised clinical management and regulatory services to the bio - pharmaceutical, biotechnology and medical devices industries.

Advantages of working with PSL in Australasia:

- Cost effective
- Streamlined and efficient regulatory processes
- Excellent recruitment and retention rates
- Medical conditions of prevalence include: diabetes, hepatitis, cardiovascular disease and cancer
- Western health system and multicultural population (English language environment)
- Highly skilled regulatory affairs and clinical trial staff trained in ICH-GCP
- Investigators conduct studies according to ICH-GCP and IND (when applicable)
- Australasia has many Key Opinion Leaders in several speciality areas
- World class Phase I facilities
- Seasonal studies in Australia and New Zealand during the off-season in the Northern Hemisphere.

CONTACT

For all enquiries please contact

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New Zealand | Australia | United States

Collective, Effective, Solutions

CLINICAL RESEARCH SERVICES INCLUDE:

- Project Management / Project Planning (Phase I to Phase IV)
- Feasibility and Site Identification
- Ethics Committee and Health Authority Applications
- Trial Initiation, Monitoring and Close-out
- Subject Recruitment and retention
- Database design
- Data Management and EDC*
- Safety Monitoring
- Protocol and CRF Design
- Laboratory Services
- Drug Management and distribution services
- Staffing solutions

*Data Management and EDC in collaboration our partner providers.

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PROVIDING PROFESSIONAL CLINICAL STAFF WHEN YOU NEED THEM

Pharmaceutical Solutions
In-sourcing Services provides experienced Clinical Research Personnel when you need them and trained to your requirements. We draw on our clinical research understanding to match the best individual for the unique requirements of your project. We then provide ongoing support and training ensuring you receive the best possible solution to your needs.

Insourcing Solutions help:

- Reach challenging deadlines
- Provide immediate resources while planning for future studies
- Manage monitoring demands of large trials
- Remedy short fall in staff, by providing temporary placement
- Provide business continuity while key staff are on leave
- Help deliver quality services through utilising our experienced specialists

Proficient, Professional, Personalised

REGULATORY AFFAIRS SERVICES INCLUDE:

- Dossier Evaluation and gap analysis
- Product sponsorship and 24/7 support
- Regulatory compliance
- New product submissions (TGA, Medsafe)
- Variations and Changed Medicine Notifications
- Quality System development and audits
- SOP development
- Promotional / advertising material reviews
- Medical and Pharmacovigilance
- Rescheduling and Reclassification submissions
- Technical product support and advice
- Product Quality Complaint management and resolution
- Recall and Crisis Management
- Section 29 management
- Prescribing information, Data Sheets and CMI's
- Labelling / artwork review and preparation
- QA product release
- MIMS updates
- US FDA IND applications.

These services span the spectrum of Prescription (Innovator and Generic), Biotechnology, Controlled Drug, Pharmacy, Grocery medicines and Medical Devices.

Commercially Focussed, Current, Responsive

BROADENING YOUR PATIENT REACH

As a Site Management Organisation, Resolute Clinical provides CROs and BioPharma with access to an expanded population of trial patients.

Established to meet the needs of BioPharma companies providing long term product data in the Primary Care setting.

Our experienced staff and network of General Practice centres provide the resources and capabilities necessary for the collection of high quality data.

Resolute Clinical builds essential connections between patients and clinical practitioners.

We offer:

- Access to General Practitioners (Primary Care)
- Dedicated study coordinators
- Royal Australian College of General Practice accredited training
- Site start up expertise
- Access to independent IRB/EC
- A strategic partnership with Australia's largest network of GPs (170 practices and 1500 GPs) ensures:
 - Rapid and large scale recruitment across many disease indications:
 - > Vaccines, Pain Management, Diabetes
 - > Hypertension, Dyslipidemia, Dementia, Mood Disorders

Site, Solutions, Service, Support

www.pharmasols.com

