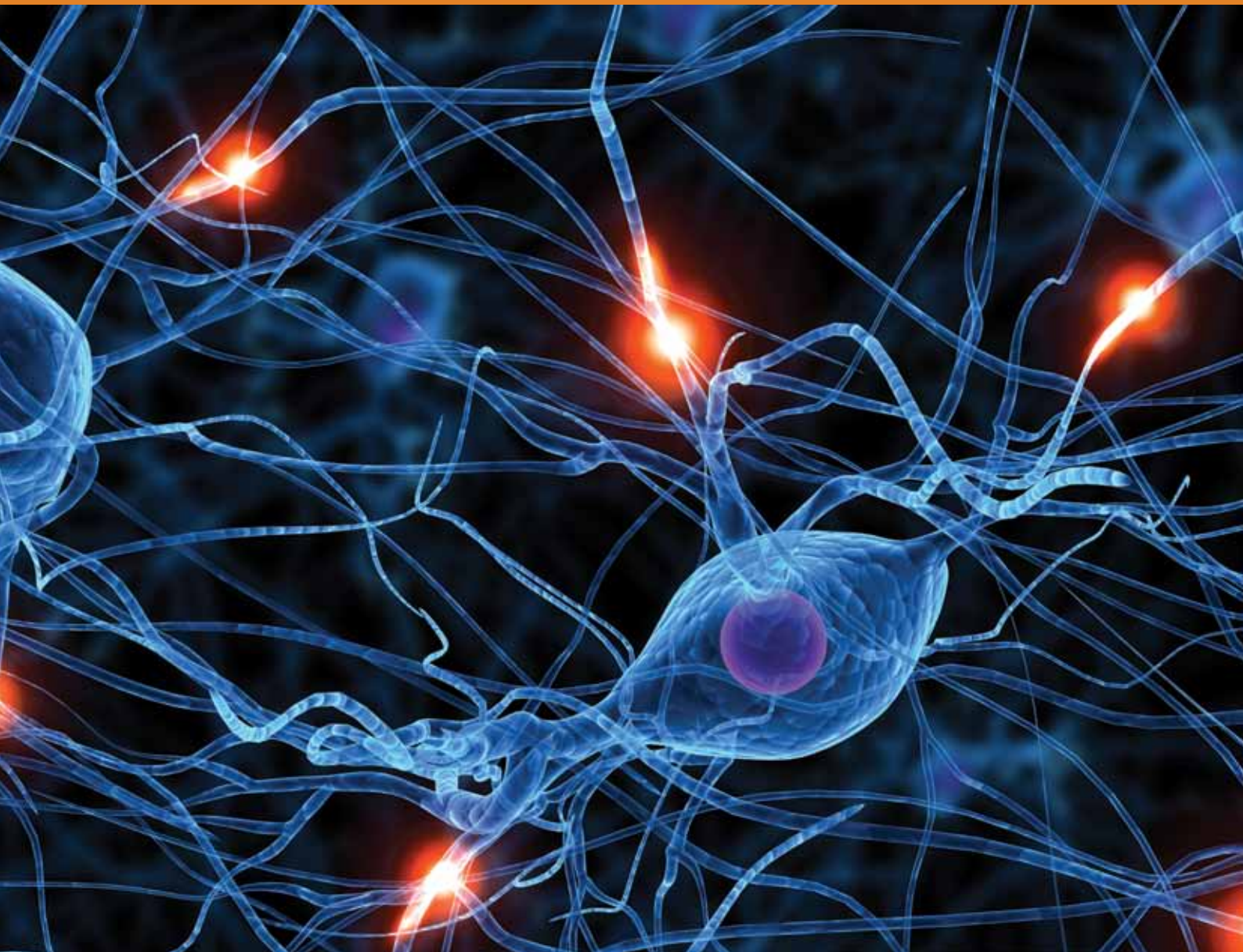


**Innovative neuroscience research –
thinking globally, working locally.**



Neuroscience Trials Australia

Neuroscience Trials Australia is an Australian-based, not-for-profit contract research organisation specialising in neuroscience clinical research.

Our superb range of services will ensure we deliver your project in a cost-effective and timely way.

Areas of expertise include stroke and stroke-related conditions, multiple sclerosis, epilepsy, Parkinson's disease, spinal cord injuries, Huntingdon's disease, neurosurgery, pain, neuromuscular disease and migraine.

As a wholly-owned subsidiary of the Florey Neurosciences Institute, we have strategic alliances with many therapeutic disease groups and we can provide access to key opinion leaders, sites and clinical trial expertise through a range of tailored services.

Our staff have global management experience in all phases of clinical research including studies sponsored by pharmaceutical companies, the biotechnology industry, granting bodies or institutions and Investigator-initiated studies.

Services offered

Study feasibility

We routinely produce feasibility reports on site availability, potential recruitment and local treatment standards. We can also produce more complex reports when required. With our direct access to the therapeutic disease groups, key trial sites and key opinion leaders, we can produce feasibility reports within very short time frames.

Project management

Our project managers are committed to ensure milestones are reached and timelines met.

The project manager serves as your primary point of contact and has direct responsibility for all aspects of the clinical trial. They are fully versed on local regulations and will assist with regulatory requirements when setting-up a study in Australia or in other parts of the world. Our project managers can provide guidance on labelling requirements, import permits and local indemnification and insurance issues.

Neuroscience Trials Australia is a registered enterprise in Australia with the Therapeutic Goods Administration (TGA) and therefore can act as your representative locally.

We can provide you with the following:

- Development, guidance and management of your clinical development programme
- Management of assigned project teams
- Project status reports and newsletters
- Management of project milestones and deliverables
- Project, monitoring, communication and recruitment plan generation and implementation
- Local regulatory advice
- Management of third party vendors
- Management of site/investigator payments and tracking.

Monitoring

Our staff have a thorough knowledge of local regulations and 'good clinical practice' processes. We adapt easily to our customers' needs. We are totally flexible and can follow your procedures or you can ask us to employ our own – it's up to you.

We can assist you with:

- Phases I to IV (in Australia or globally)
- Site feasibility and identification
- 'Investigator' and 'monitor' meeting preparation and set-up

- All types of monitoring visits including site selection, initiation, routine and study-closure visits
- Local regulatory submissions
- Obtaining local HREC/EC/IRB approvals
- Site management
- Good clinical practice (GCP) training
- Monitoring, communication and study-plan generation and implementation
- Query resolution
- Blinded and unblinded investigational product accountability
- Subject recruitment plans and implementation.

Medical writing

We provide a comprehensive array of clinical trial-related medical writing services in accordance with applicable regulations and guidelines such as:

- Investigators' brochures
- Study protocols
- Participant information forms
- 'Case report form' completion guidelines
- Clinical study reports
- Policies
- Standard operating procedures.

Data Management and Biostatistics

We offer a wide range of services including:

- Study design
- Sample size calculations / power analyses
- Interim analyses and statistical monitoring
- Writing/reviewing statistical sections of protocols
- Randomisation schedules
- Programming of tables, listings and figures
- Interim analyses
- Statistical analyses
- Design of 'case report forms'
- Design of database and entry screen and maintenance
- Data Management Plans
- Specification of data structures and data handling procedures/validation
- Validation/Consistency check programming.

Regulatory

The Australian clinical regulatory system is renowned for being fast, fair and accommodating. The system works by a Clinical Trial Exemption (CTX) or Clinical Trial Notification (CTN), with the vast majority of trials undertaken in Australia falling into the latter category. All trials must have an Australian sponsor.

The sponsor takes overall responsibility for the conduct of the trial and signs either the CTN form or the CTX form.

As Neuroscience Trials Australia is a registered enterprise with the Therapeutic Goods Administration, we are able to act as the Australian sponsor for customers who do not have a legal entity within Australia.

Safety

Safety is paramount during all phases of clinical research. We can provide the following medical monitoring services:

- Medical support to sites for study protocol interpretation and subject medical management
- Medical review and assessment of serious adverse event reports
- Preparation of serious adverse event narratives for regulatory reporting or inclusion in clinical study reports
- Assistance with, and participation in, Data Safety Monitoring Boards
- Timely receipt and processing and communication of initial serious adverse event reports and follow-up to case closure
- Safety reporting in compliance with local regulatory requirements
- Preparation and distribution of investigator notification letters.

Talk to us today and let us help you deliver a cost-effective, reliable and high quality project. You will be served by industry veterans employed by a highly respected research organisation, the Florey Neuroscience Institutes.

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