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AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

neuroscience trials australia

Neuroscience Trials Australia

Company Description

Neuroscience Trials Australia is an Australian-based, niche, not-for-profit contract research organization (CRO) specializing in neuroscience clinical research. We work on global or local projects.

Therapeutic areas of expertise include epilepsy, stroke and stroke-related conditions, multiple sclerosis, Motor Neurone Disease (MND), Alzheimer's disease (AD)/cognitive disease studies, Parkinson's disease, spinal cord injuries, neuro oncology indications such as DIPG and GBM, Huntington's disease, neurosurgery, pain, neuromuscular disease and migraine.

As a wholly owned subsidiary of The Florey, Neuroscience Trials Australia (NTA) has strategic alliances with many therapeutic disease groups and we can provide access to key opinion leaders, experienced sites and clinical trial expertise through a range of tailored services. Any profit that we may make on a project is re-directed back into neuroscience academic research.

With an average of 12 years industry experience, our staff has global management expertise in all phases of clinical research including studies sponsored by pharmaceutical and device companies, the biotechnology industry, granting bodies (such as the USA NIH or Australian equivalent NHMRC), collaborative groups, institutions and Investigator-initiated studies.

Pipeline and Developments

Neuroscience Trials Australia provides the following advantageous environment for your project:

- Clinical Trial Network Affiliation: a unique aspect of our business that allows up to keep the capabilities databases, assist with feasibility and co-bid for projects with our neuroscience trial networks. Examples include: stroke (Australasian Clinical Trial Network/ASTN), cognition/dementia (AC4R), multiple sclerosis (MS Research Australia), Australian Epilepsy Clinical Trial Network (AECTN) and Movement Disorders Society of Australia (MDSA),
- NTA experienced, neuroscience specialized team with extensive knowledge of the proposed sites and local regulatory environment;
- NTA expertise in studies involving imaging (CT, MRI, PET) and collection of biomarker samples;
- Advantageous regulatory environment (no IND required) and short start-up times due to centralized ethics submissions;
- All potential sites have direct access to imaging facilities at and on their site;
- Overall competitive and low pricing model with no margin added for third party vendor associated pass-through costs;

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- Access to and use of regulatory (FDA) compliant data management and biostatistics ensuring your study data is of the highest standard and can be used in subsequent regulatory applications and submissions.

Our core resource capabilities include Project Director/Project Managers, Clinical Research Associates and Clinical Trial Administrators. In addition, we have biostatistical capabilities and alliances with various data management vendors.

All of our work is undertaken utilizing either our own suite of Standard Operating Procedures or those of our clients. Our team is trained in Good Clinical Practice Principles and we work according to global regulatory standards (including projects under IND/Food and Drug Administration (FDA) expectations).

Our capabilities include:

- Clinical Trial Network Affiliation;
- Imaging studies expertise;
- Biomarkers and Bio banking: the majority of our studies involve these requirements and thus the same applies here;
- Study design: protocol (and associated documents) and Investigator brochure preparation or finalization;
- Start-up activities: site selection and feasibility, preparation and submission of Institutional Review Board/Ethics applications, Investigator meetings, contract negotiation;
- Site Initiation, monitoring, site management and close-out activities;
- Investigator meeting organization, participation and management;
- Third party vendor selection and management;
- Project Management;
- Study budget negotiation (sites and vendors) as well as budget management;
- Data management expertise with internal and external vendor capabilities;
- Biostatistician who is a specialist in neuroscience projects;
- Medical Monitoring capabilities; utilizing only neurologists for this service as required;
- Data Safety Management Board selection, preparation of associated documentation, maintenance and assistance in report preparation;
- Regulatory: assistance in preparation of IND packages, attendance at pre-IND, End of Phase 2 meetings, pre-NDA meetings;
- Medical writing including Clinical Study Report preparation;
- Preparation of Standard Operating Procedures;
- Training of site and study personnel in Good Clinical Practice.

What we are looking for:

Companies that are interested in bringing their clinical trial development plans to Australia to take advantage of the well represented CNS/neurology networks, capabilities and experienced sites.

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Contact:

Name: Tina Soulis
Position: Chief Executive Officer (CEO)
Company: Neuroscience Trials Australia
Address: 245 Burgundy Street, Heidelberg, Victoria, Australia 3084
Website: www.neurotrialsaustralia.com
Phone: +61 3 429 300 705
Email: tina.soulis@florey.edu,au and athina.soulis@unimelb.edu.au.