

A STUDY PROTOCOL AND PER PATIENT BUDGET REVIEW PROCESS PROPOSAL for EPILEPSY CLINICAL TRIALS

NTA was established to facilitate and support clinical research, particularly investigator initiated research, across the neurosciences and enjoys official endorsement by the Australian and New Zealand Association of Neurologists. Representatives from each of nine specialty groups sit on the NTA Management Board, including Sam Berkovic on behalf of epileptologists.

NTA has helped develop a study protocol and budget review process based on that provided via the Australasian Stroke Trials Network and now adopted by the Movement Disorder Society of Australia Clinical Research and Trials Group (MDSACRTG) and the Multiple Sclerosis Research Australia Clinical Trials Network (MSRACTN). This approach is of value to (i) study sponsors, they gain access to experts with an intimate understanding of the therapeutic area and local issues relating to study feasibility, (ii) clinicians, who benefit from an effective single communication channel, and (iii) the clinical group or society, as the authoritative group on clinical research in that specialty area. The process involves a review by a panel drawn from the specialist groups of the scientific merit and local feasibility of the study. NTA provides administrative assistance to arrange the review and in determining and negotiating with the sponsor a suitable per patient payment budget. **The fee charged for this service is paid in its entirety to the specialist group/society/network.**

NTA makes available administrative support services to each of the specialty groups. Building on initial federal funding NTA is now self sustaining and generates revenues from a range of contract research services in both the investigator initiated and commercially sponsored trial domains. In addition NTA is building a central research fund with a plan to use the annual investment income to seed fund early stage academic clinical research across the neurosciences. The NTA research fund is built up via a 3% service fee on commercially sponsored study per patient payments when negotiated by NTA on behalf of the specialty groups and importantly when that leads to an increase in the per patient payments so that sites are not disadvantaged.

In the coming 6 months we will be announcing a range of clinical trial management tools currently in development, which we plan to make available free of charge to neuroscience clinicians through their membership of the nine specialty groups including the ESA. The software will include billing, patient tracking, data management, randomisation, and other modules. We currently provide study project management advice, protocol development, monitoring and data management services on a cost recovery basis to directly support investigator-initiated studies and are also investigating ways to make available a Biostatistical advisory service to support clinicians at the clinical trial design stage.

I look forward to building on this important relationship between NTA and the ESA and can be contacted most days on 03 9496 4482 (Monday to Thursday) or 03 9342 8070 (Friday).

Kind regards



Peter Keller MBA, MHEth, PhD
Chief Executive Officer
Neuroscience Trials Australia
tel + 61 (0)3 9496 4482 (NSRI)
tel +61 (0)3 9342 8070 (RMH)
fax + 61 (0)3 9496 2650
web <http://www.neurotrialsaustralia.com>