
RESOURCES AND ASSISTANCE FOR INCLUDING GENOMIC ANALYSES IN SLEEP CLINICAL TRIALS

Genetic material can be collected and banked in a clinical trial for genetic analysis which is part of that particular trial, and also for a wider collection of genetic material for later use in identifying relationships between gene polymorphisms and a range of sleep conditions.

The ASTN provides infrastructure for banking genetic material through the expertise and facilities of ASTN Chief Investigator Professor Lyle Palmer and his team at the University of Western Australia's Centre for Genetic Epidemiology and Biostatistics, (www.genepi.org.au). Lyle's group, which leads a number of NHMRC-funded national enabling facilities, can advise trials researchers on the utility and logistics of collecting genetic material in a proposed trial. They can also help with procedures for collecting, banking and tracking samples, model patient information and consent forms, and standardised minimum data which should accompany specimens and entry to metadata files.

The ASTN Research Committee links research groups to these resources as part of the assistance it provides for development of clinical trials protocols.

To find out more about ASTN infrastructure for genomic analyses, contact Dr Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au).

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ASSESSING THE FEASIBILITY OF CLINICAL TRIALS OF SURGERY FOR SLEEP DISORDERED BREATHING

An important message from a March 2008 ASTN workshop on clinical trials in surgery was that preliminary surveys can be a useful tool in the assessment of possible trials for feasibility. Professor Michael Solomon and Associate Professor Jane Young of the Surgical Outcomes Research Centre at the University of Sydney pointed out that clinical trials are most likely to be successfully completed if, for example, they address questions that are widely recognised by surgeons as needing answers, and if patients can readily be enrolled. A preliminary survey or census of surgeons can be used to assess factors such as clinical equipoise and the likely recruitment of patients for a range of possible trials. Those trials with a high likelihood of completion can then be selected for further development and implementation.



Dr Keith Wong and Dr Nat Marshall discuss survey methodology with A/Prof Jane Young

Drs Nat Marshall and Keith Wong of the Woolcock Institute in Sydney and participants at the workshop are currently working with surgeon and sleep physician colleagues to gain funding for a census of sleep surgeons in Australia. This census will collect information on surgeons' clinical workloads, their opinions on the relative importance of various questions in the field that could be answered by clinical trials, their opinions on clinical approaches and their willingness to enrol patients in clinical trials. The census will use an extensive two-stage opinion survey methodology, developed by the Surgical Outcomes Research Centre, which has been integral to the successful development and conduct of clinical trials in other surgical disciplines. The ASTN is very grateful for assistance from Jane Young and colleagues on the use of this methodology.

Medicare billing data will also be used to assess the volume of sleep surgery undertaken in Australia over the last ten years.

To find out more, contact Dr Nat Marshall (nmarshall@med.usyd.edu.au) or Dr Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au).

ASTN STAKEHOLDER SURVEY

The ASTN conducted a stakeholder survey in May 2008. A brief report on this survey appears below and more detail is available from ASTN National Research Manager Melanie Harris (melanie.harris@rgh.sa.gov.au).

The ASTN Executive Committee thanks those who provided feedback through the survey and welcomes further feedback at any time. Executive Committee membership and contact details are given at http://www.sleeptrials.net/exec_committee.htm.

ASTN Stakeholder Survey: Brief Report

Background

A survey of ASTN stakeholders was held so that views from interested sleep researchers could be used in network planning. Key areas for questions were support for clinical trials, enhancement of capacity for conducting clinical trials, and equitable access to infrastructure.

An email invitation with a link to an internet-based survey was sent on 14/05/08 to approximately 115 researchers who had been in contact with the ASTN. Fifteen survey responses were obtained by 31/05/08 and these are summarised below.

Summary of responses

Respondent categories

Newer clinical trials investigators	7	Research field: Sleep and breathing	12
Experienced investigators	4	Research field: Clinical sleep psychology	2
Interested but with no experience	4	Research field: Circadian	4

Involvement with the ASTN

Receiving newsletters or mailings	14	Contributing to trial development	7
Attending Open Forums	12	Receiving help to develop a trial	5

Stakeholder satisfaction scores

Support for trial development

Most answers showed satisfaction* with help for protocol development and grant applications (11 of 13 responses) and with information on genetic analyses in trials (6 of 9 responses). Remaining responses were neutral except for one *Fairly dissatisfied* for provision of information on genetic analyses in trials. Only 5 of 11 were satisfied with help for finding additional trial sites, with 6 neutral.

Enhancing capacity

Eleven of 15 were satisfied with educational activities and the remainder were neutral.

Accessibility

All 15 respondents were satisfied with provision of information on ASTN services and meetings. Thirteen of 15 were satisfied that ASTN services were easily accessible, with 2 neutral.

Additional comments

Suggestions volunteered by respondents were:

- > vision meetings to identify important trials for conduct by the ASTN
- > clarifying processes for groups developing protocols with the ASTN
- > identifying alternative funding for proposed trials

* The two most favourable assessment options "Very satisfied" and "Fairly satisfied" offered in the 5-option Likert type scale are combined here for simplicity.

Pointers for ASTN planning

The low level of negative responses can be taken as an indicator of more general opinion as it is likely that any significant negative viewpoints would have been given.

While numbers are small, responses suggest that at least for researchers interested in the ASTN, the organisation is performing fairly well in supporting the development of new trials, enhancing the capacity for sleep researchers to conduct clinical trials and in making ASTN infrastructure available in an equitable way.

The ASTN Executive should look at whether information on genetic analyses in trials and help in finding additional study sites can be provided more effectively. Additional suggestions on trial visioning, functioning of trial development groups, and alternative funding for trials, should also be considered.

The generally positive response also suggests that the ASTN Executive should continue with current methods of obtaining feedback and suggestions from the research community, for example by inviting comment on ASTN newsletters and verbal reports at half-yearly ASTN Open Forum meetings.

The ASTN is funded by an NHMRC Enabling Grant to facilitate investigator-initiated multicentre clinical trials in sleep health. It covers the full range of sleep disorders, including insomnia, circadian disturbances and neurological disorders as well as sleep breathing disorders.

Visit the Australasian Sleep Trials Network website at www.sleeptrials.net to see:

- assistance provided by the ASTN including biostatistics, study design, health economics, genetics and protocol development
- what to do to discuss a study idea with the ASTN
- how the ASTN is managed
- reports from ASTN Open Forums
- ASTN newsletters
- news about upcoming ASTN events