MEDIA RELEASE

NSANZ to lead development of Australian Neuromodulation Device Registry

Sydney, 1 June 2023 – the Neuromodulation Society of Australia and New Zealand (NSANZ) today announced plans to develop a centralised digital platform for the collection and analysis of long-term clinical outcome data associated with a range of neuromodulation therapies.

NSANZ President Dr James Yu said: "The Australian Neuromodulation Registry will be the first device registry to be established outside Europe, and only the third to be established since the modern era of neuromodulation commenced in the 1960s.

"Moreover, it will position Australia as a world-wide leader in clinical data collection, ahead of medical technology powerhouses North America, Japan, Switzerland, Israel, Germany, France, and China".

Neuromodulation devices and their related medical technologies alter nerve activity by delivering electrical or pharmaceutical agents directly to a target area of the brain, spine or peripheral nerves.

Neuromodulation's therapeutic scope is broad and includes restoration of profound hearing loss (cochlear implants), restoring bowel and bladder control (sacral nerve stimulation), alleviating symptoms of Parkinson's disease (deep brain stimulation) and providing relief from chronic pain (spinal cord stimulation, or SCS).

"Medical device registries help bridge the gap between observed performance in the real world versus the engineered environment of the clinical trial. They record outcomes against many non-select patients over several years, instead of a small number of select patients over a few months", said Dr Yu.

"But they are time-consuming and costly to develop and maintain, requiring a multi-year collaborative effort between clinicians, device manufacturers, government, regulatory authorities, and patient advocacy groups", he added.

When implemented, the Australian Neuromodulation Registry (ANR) will be the second device registry to be established by a regional chapter of the International Neuromodulation Society (INS).

INS President Dr Marc Russo said: “Neuromodulation is a fast-evolving, flexible medical technology used to treat highly diverse patient populations for a wide array of chronic underlying conditions.

“Indeed, the heterogeneity of application to the individual is a key strength of this innovative therapeutic modality, hence is increasingly the focus of innovations like programmable, wave-form spinal cord stimulators for chronic pain.

“For this reason, it’s challenging to design and execute randomised clinical trials (RCTs) with robust, general applicability. This increases the relative value of pragmatic real-world evidence (RWE) derived from large patient-outcome registries.

“Multi-manufacturer device registries like those implemented by the UK/Ireland chapter of the INS, and soon, the Australian chapter, will build on the work of single manufacturer global, prospective multi-centre databases such as RELIEF[1].

“By harnessing the power of aggregated data, clinicians and researchers can evaluate the efficacy of different devices and therapeutic approaches and develop evidence-based guidelines for optimal patient management”.

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[1] Earlier this year, the Pain Management Journal published research on RELIEF’s clinical outcome data for a total of 1289 SCS patients implanted across 70 centres. After three years, 98.9% of patients continued with their SCS because it provided adequate pain relief with a high-level of safety and a low rate of explant/serious adverse events.