Neurosurgery SIG: Proposal for CDISC Pilot Study

Background:

At the SIG meeting in Dublin, June 2012, it was agreed that the group should plan to endorse a common rating scale for assessing adverse events associated with neurosurgical implantation of DBS systems in Parkinson's patients at the 2013 meeting in Sydney.

A project to develop such a rating scale was initiated at the Paris meeting in 2009 by a working group within the Neurosurgery SIG (previously known as the Neurosurgery Task Force). Preliminary work prepared by 2 of the 5 working group members was presented at the meeting in Toronto in 2011. However, no further action has been taken on this project. NINDS in collaboration with CDISC has prepared a data capture module for the AEs associated with neurosurgical implantation of DBS systems in PD patients. This data capture module has been released as a provisional standard for use in December 2012.

Recommendations:

1. The Neurosurgery SIG agrees to adopt the NINDS/CDISC data standard for capturing AE data associated with DBS in Parkinson's patients.
2. The Neurosurgery SIG tests this new data capture tool in an epidemiological study

Objectives:

To conduct a pilot test of this CDISC module in an epidemiological study to be conducted at 10-15 clinical centers world-wide in order:

1. To assess the usability of the data capture module and to provide feedback to the CDISC organization
2. To analyse the data in order to identify the parameters most frequently associated with various types of AEs associated with the neurosurgical implantation of DBS systems in PD patients. Parameters to be analysed include:
    a. Anatomical target
    b. The use of microelectrode recording
    c. Infection rates and use of prophylactic antibiotics
    d. Intra-operative patient management: position, local vs. general anesthesia

Methods:

Each participating study site will complete the PD CDISC module for all consecutive patients deemed eligible for DBS for Parkinson's disease at the study center over a defined period of time (TBD and at least 1 year). Each patient will be followed up for 3 months after DBS system implantation.

An electronic case record form (CRF) will be developed in order to allow data entry from any site world-wide.

Planned Deliverables:

- Presentation and publication of the data generated from the study.

Next Steps:

- Identify interested study sites world-wide who will be responsible for obtaining local ethics approval and for all local expenses associated with the conduct of the study.
- Seek research funding in order to support data collection and analysis
- Protocol development