



Laser Ablation of Abnormal Neurological Tissue  
using Robotic NeuroBlate<sup>®</sup> System (LAANTERN)  
Prospective Registry

**Statistical Plan**  
**June 2020**

**NCT02392078**

## **LAANTERN Statistical Methods**

### **General Summary**

Descriptive statistics will be used to summarize the patient population data, operative data, and follow-up data. For continuous variables, the total count, mean, standard deviation, minimum, and maximum will be provided. For categorical variables, the total count and percentage will be provided.

### **Survival Analysis with Censoring/Truncation**

The survival analysis will be used to estimate time-to-event probability and will take into account right-censoring or left truncation. Left truncation occurs when patients are enrolled into the study after the NBS Index Procedure occurs. The survival function will be estimated using the Kaplan-Meier method. The hazard rate over time may be provided along with corresponding 95% confidence limits to assess potential time-dependent trends.

### **Comparative Analysis**

Comparisons in survival/event rates may be made between subgroup of patients with various disease states (for example, epilepsy vs tumor, etc.), differences in baseline demographics, product models (for example, new device iterations, etc.), or other factors that are deemed important for understanding patient outcomes or risk.

### **Proportional Hazards Regression**

The proportional hazards regression models may be used for time-to-event analysis. Predictors may include patient baseline variables in addition to the risk factor of interest.

### **Determination of Patients for Analysis**

All enrolled patients who had procedures with the NBS will be included in this analysis. Additional analyses may be performed for subgroups of interest based on all enrolled patients with valid data.