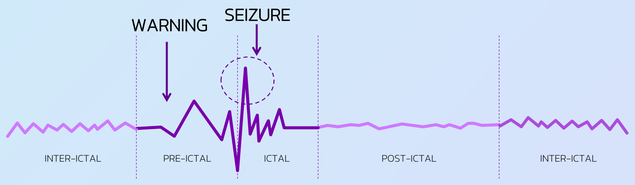
Validation of medical device mjn-SERAS for early detection of epileptic seizures in refractory epilepsy patients in a normalized environment: A prospective, multicentre, clinical study.

INTRODUCTION

The use of an ear-EEG device (**mjn-SERAS**) will allow the recording of brain activity and the data process by the MJN's AI algorithm to **anticipate seizures**. The device may then be able to **generate alerts about seizure risk** enabling people with epilepsy to take evasive action and reduce seizure impacts.

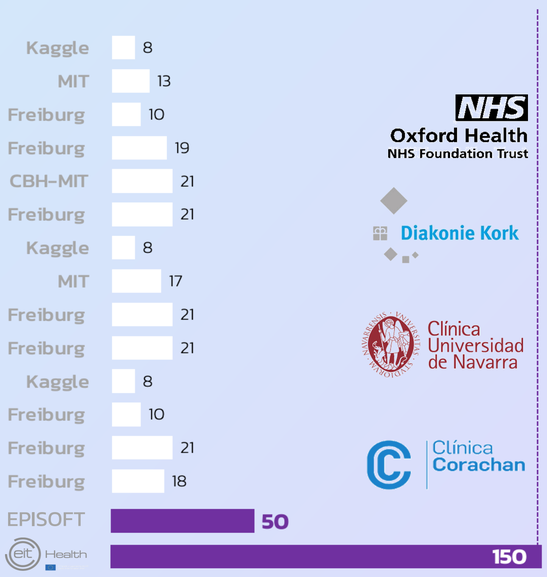


REAL-TIME
SEIZURE RISK
ASSESSMENT

METHODS

A prospective, **multicentre, clinical trial** to validate mjn-SERAS medical device, CE marked in Europe by BSI Group, in the participant's normalized environment. In **individuals over 2 years** of age, with a diagnosis of refractory epilepsy. We will **determine the impact of the mjn-SERAS** device on the early detection of seizures. **n=150** subjects with a control group. Patient's quality of life, safety, reduction of accidents, and also sensitivity, specificity, positive predictive value, PPV and F-Score of the device will be analysed.

EPILEPSY PREDICTION CLINICAL TRIALS



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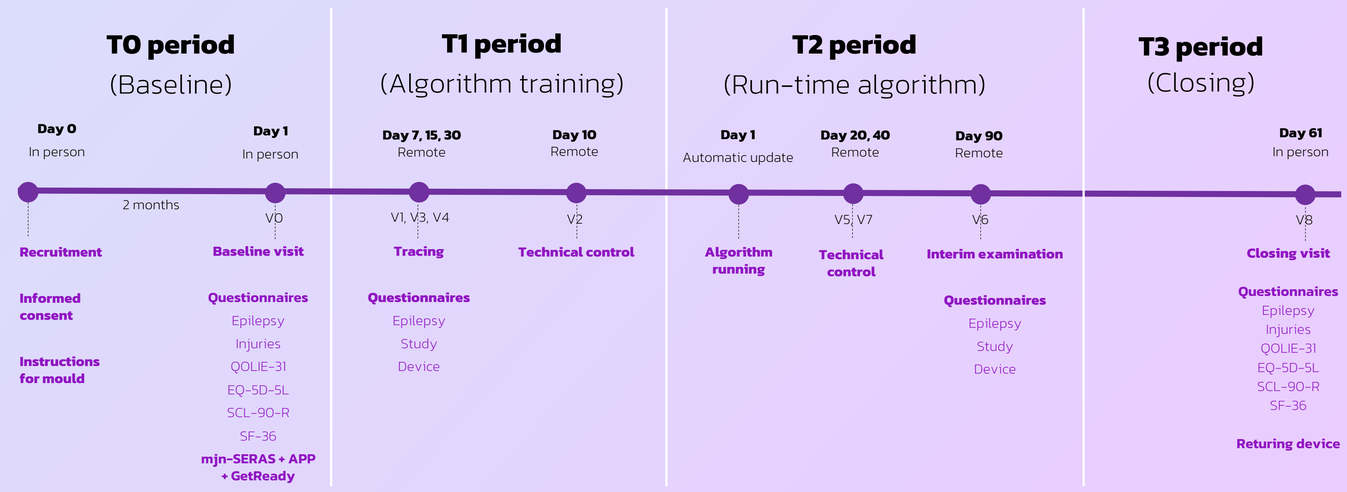
TIMELINE



RESULTS

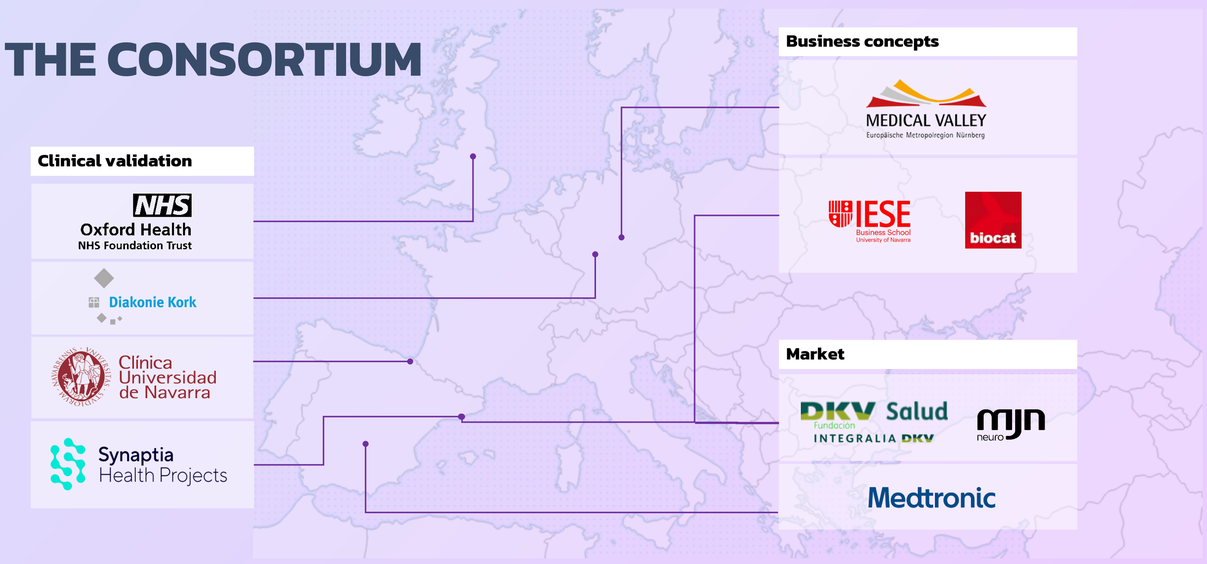
Expected results of the study are:

75% Sensitivity	**> 75%** F-Score Assimilated to specificity	**> 50%** Positive Prediction Value
< 1/day False Alarm Rate	**20%** Reduction of caregivers need	**20%** Improvement of quality of life

CONCLUSIONS

This study will **evaluate the mjn-SERAS** device during the day to day life of individuals with epilepsy. We aim to analyse the ability of the device to accurately predict seizures and compare these data to participant/carer recorded clinical events. Additional measures of quality of life will help determine whether seizure prediction using this tool, with its inherent risk of false positive alarms, improves the holistic well being of people with epilepsy.

THE CONSORTIUM



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