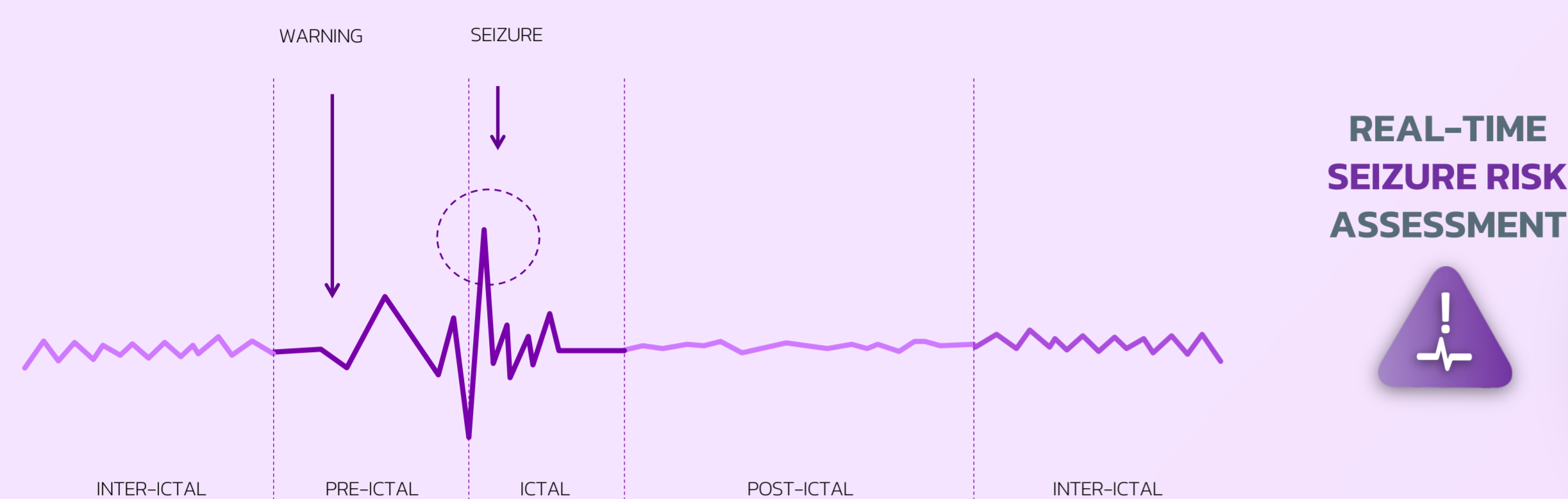


Validation of medical device mjn-SERAS for early detection of epileptic seizures in refractory epilepsy patients in a normalized environment: A prospective, multicenter, pilot clinical study protocol

INTRODUCTION

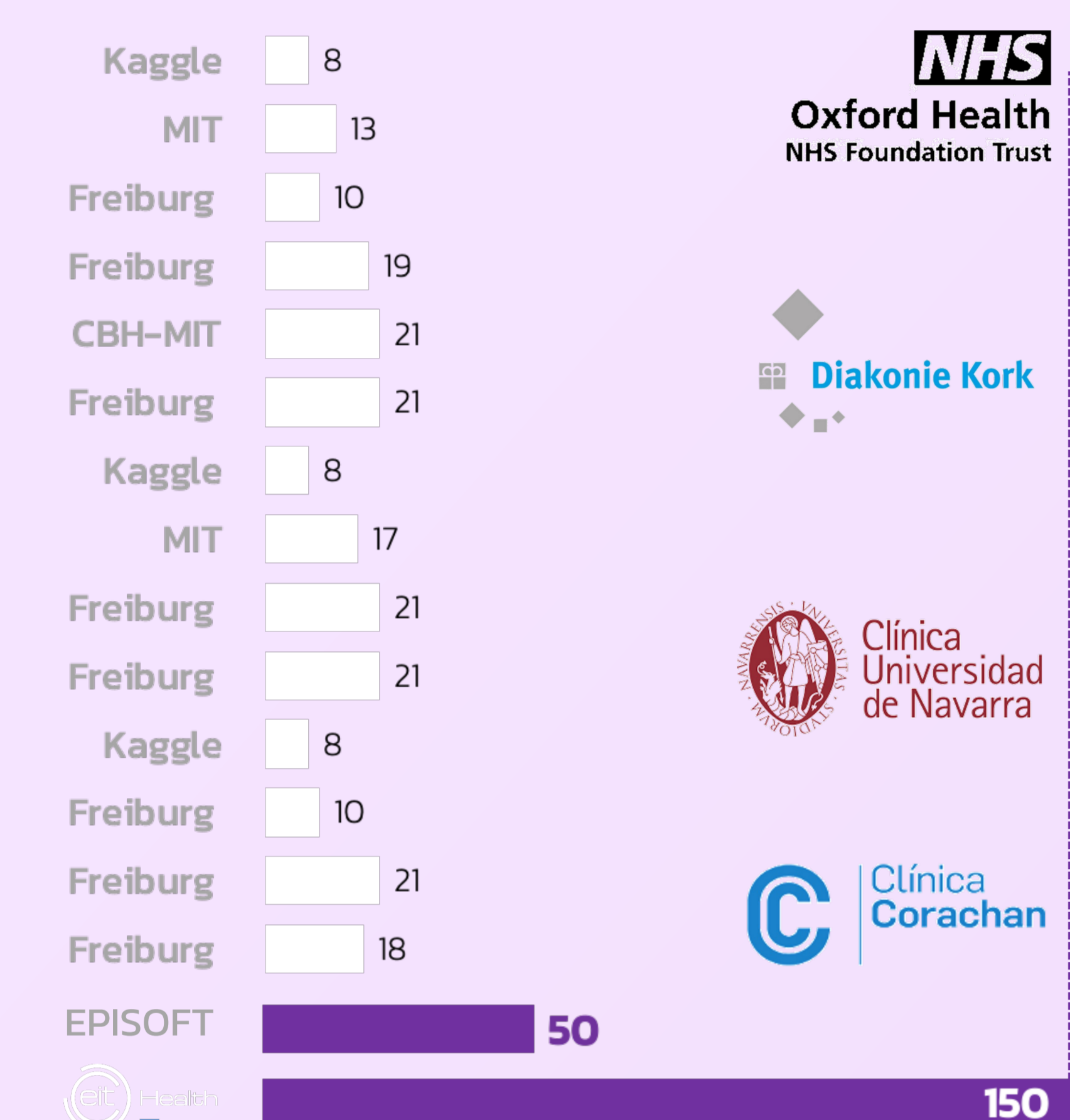
We hypothesized that the use of an in-ear EEG device (**mjn-Seras**) will allow the recording of electroencephalographic activity and the subsequent processing of the data by the artificial intelligence algorithm of MJN to **anticipate seizures** in those previously diagnosed with epilepsy. The device may then be able to **generate alerts about seizure risk** enabling people with epilepsy to take evasive action and reduce seizure impacts.



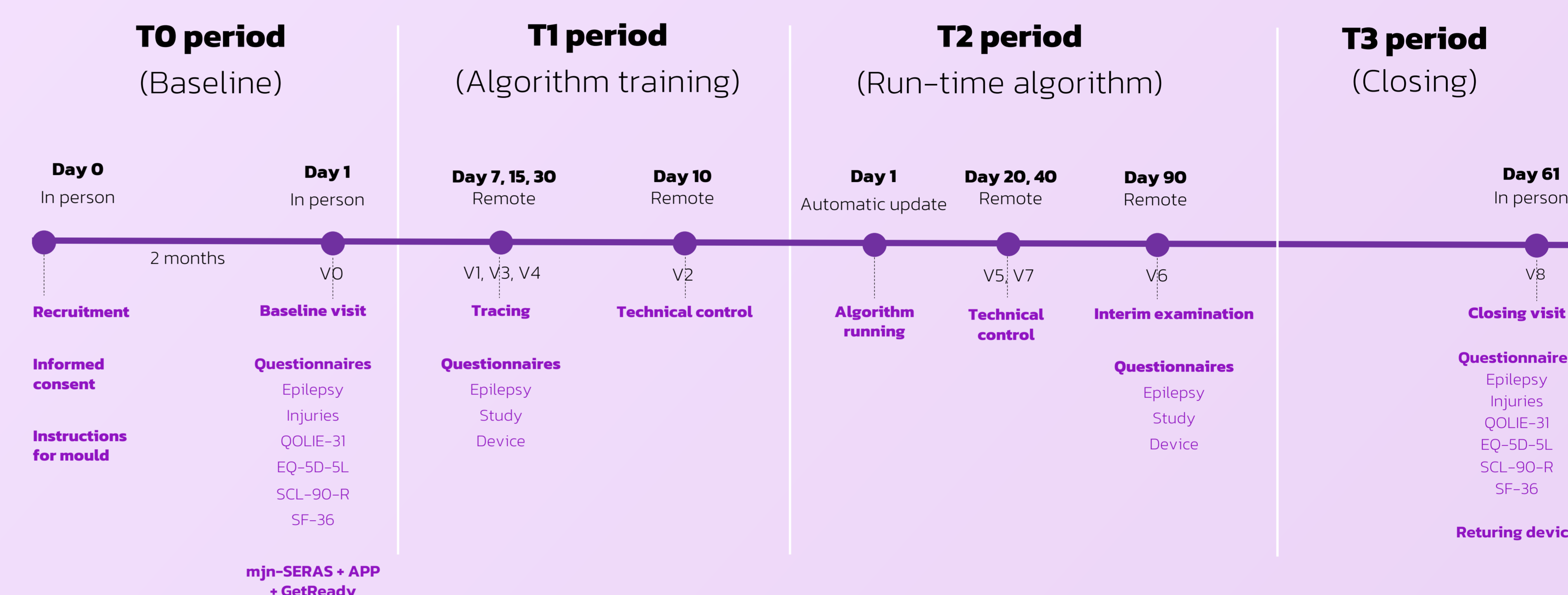
METHODS

A prospective, **multicentre, pilot clinical trial** is proposed to validate a medical device (mjn-SERAS device), which has already been certified in Europe by BSI Group (CE2797). This new validation will be 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 and the generation of a pre-seizure alert with a time window of a minimum of 1 and a maximum of 15 minutes. The sample size determined is an **n=150** exposed individuals who meet the inclusion criteria. The sensitivity, specificity, positive predictive value, PPV and F-Score of the device will be analysed. Also, the degree of satisfaction of patients and their caregivers, including the impact on quality of life and the degree of health perceived by the caregiver when alarms are generated to assess the possibility of a new epileptic seizure will be assessed. Finally, we will describe possible improvements in indicators of social relationships in different areas of personal development.

EPILEPSY PREDICTION CLINICAL TRIALS

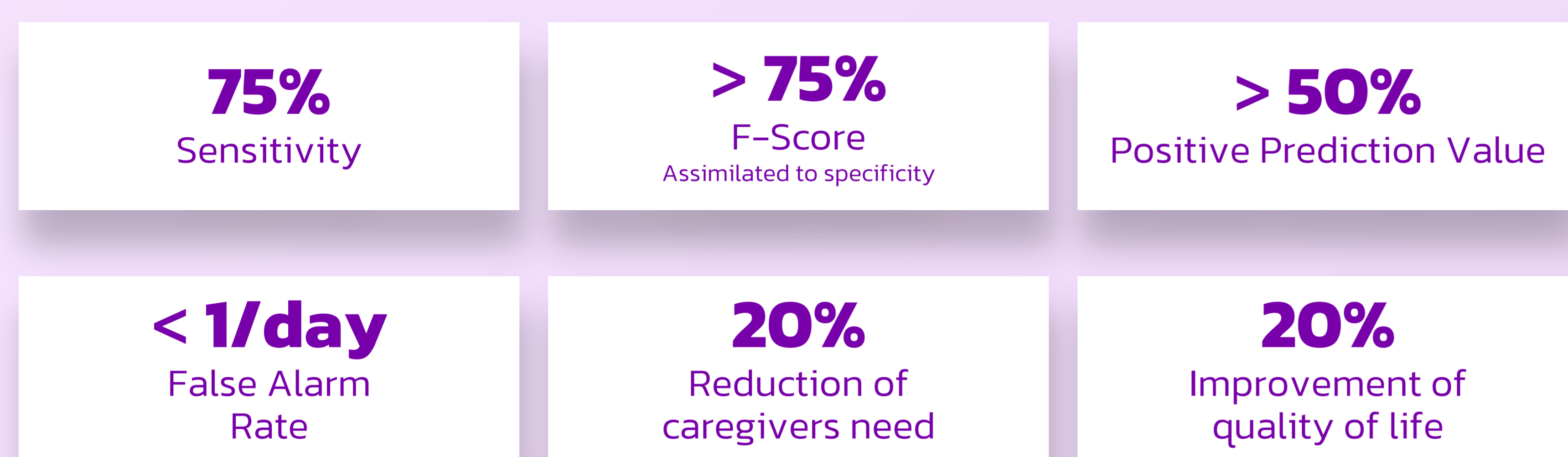


TIMELINE



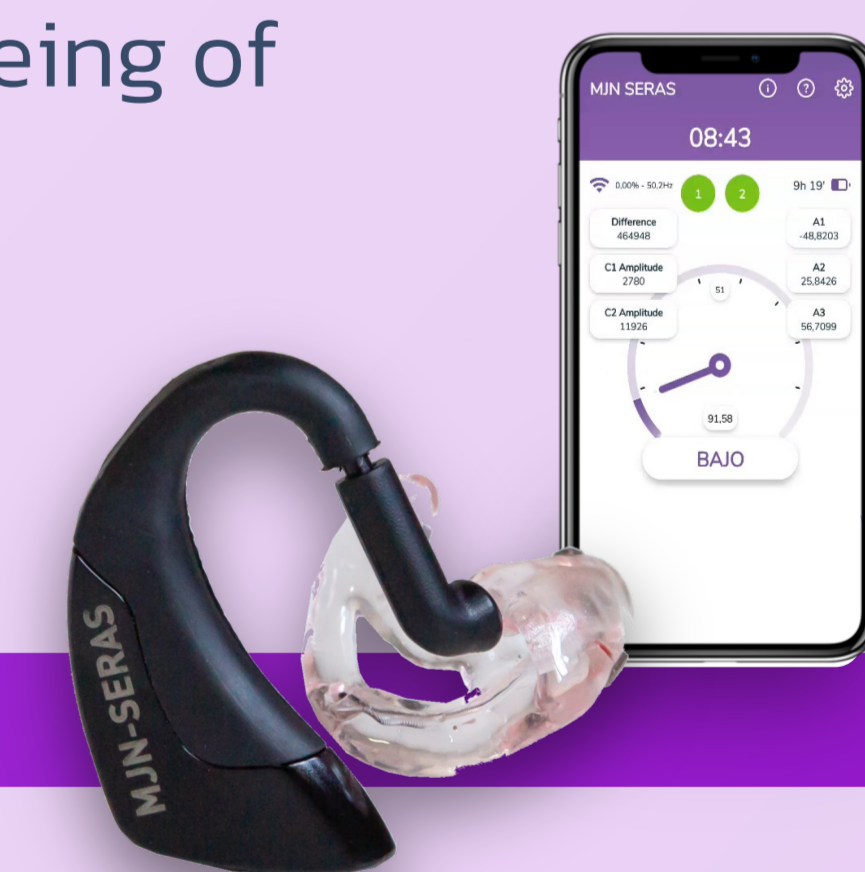
RESULTS

Expected results of the study are:

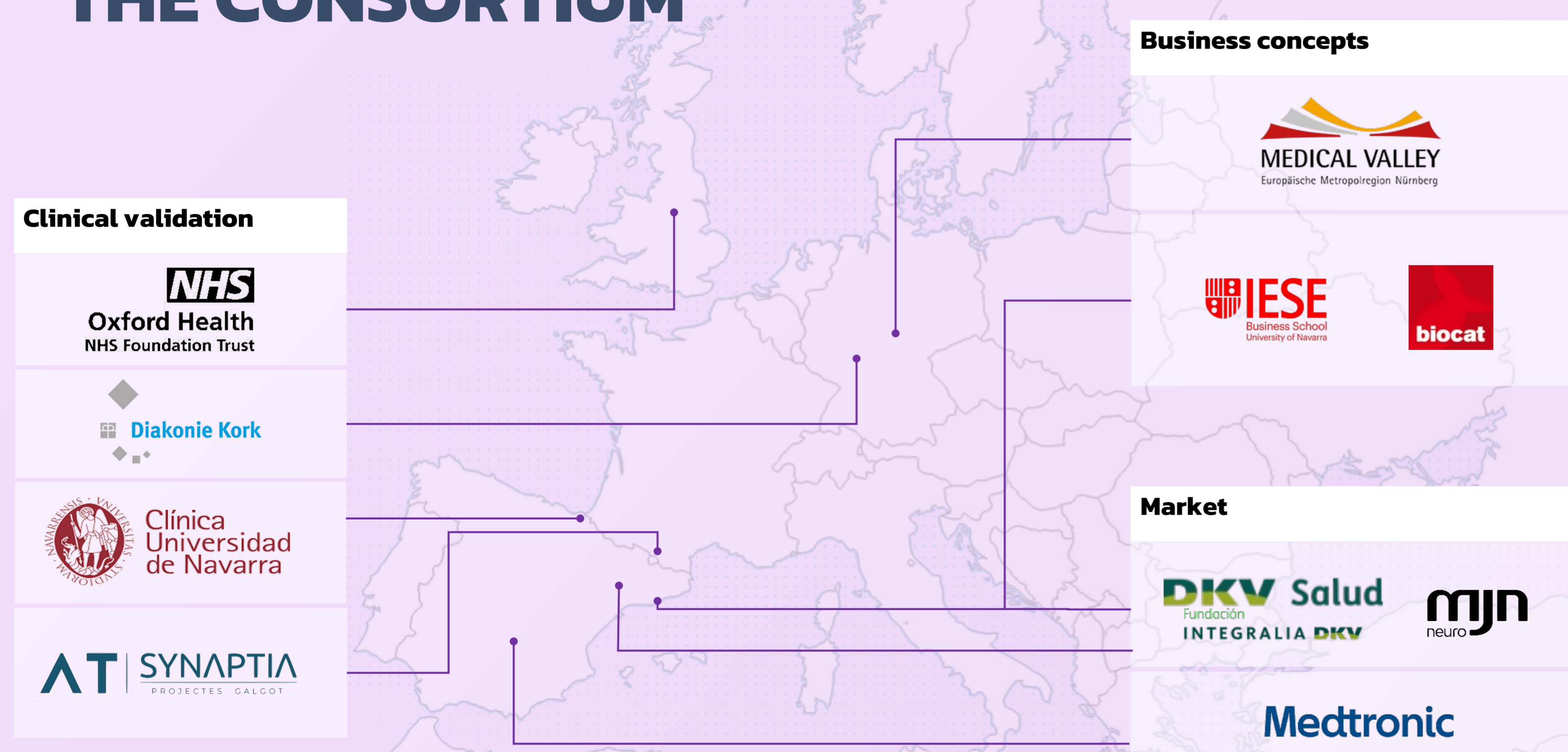


CONCLUSIONS

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



AUTHORS

Arjune Sen¹, Gustavo Torres-Gaona², Asier Gomez³, Bernhard J Steinhoff⁴, Ángel Aledo-Serrano⁴, David Blázquez⁵, Adrián Trejo⁶, Antonio Gil-Nagel⁷

¹John Radcliffe Hospital, Oxford, UK, ²Corachan Clinic, Barcelona, Spain. ³CUN Navarra, Madrid, Spain. ⁴Diakonie-Kork, Kehl-Kork, Germany. ⁵H.U. Vithas Madrid, Spain. ⁶MJN Neuroserveis, Girona, Spain. ⁷Synaptia Health Group, Barcelona, Spain. ⁷Hospital Ruber Internacional, Madrid, Spain.