

# TAYS NEUROLOGY POLYCLINIC 48-MONTH CLINICAL USAGE FOLLOW-UP REPORT

SOENIA® Medical Diary & Cloud

## Study information:

Pilot name: "Digital Seizure Diary", original pilot duration 5/2015 - 6/2016

## Study mandator

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## Principal investigator, coordinator and study site

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### Study site

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Researchers: professor, clinical epileptologist, consulting neurologist Jukka Peltola, MD PhD;  
Epilepsy (specialist) nurse Satu Hietala



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## Purpose

The purpose of this 48-month clinical usage follow-up report of the original clinical trial patients is to document **patient adherence** and **long-term usage as a prescribed medical device** smartphone application and cloud solution.

## Background information

At present, epilepsy patients report their seizure outcomes and possible treatment related adverse effects to neurologists in order for them to make informed treatment decisions. The patients provide documentation and explanation of their seizures and their side effects by communicating in one or more of the following ways: 1) oral explanation during an office visit **without any documentation**, 2) through a **pen-and-paper diary** hand delivered during office visits, 3) through **pre-scheduled phone consultations** with a specialist nurse, or 4) through **unscheduled patient-initiated phone consultations** with a specialist nurse. In general, the phone consultations are time consuming, especially the unscheduled ones.

### Present Method of Epilepsy Patient Management

In Tampere University Hospital's (TaUH) Department of Neurology there are two types of epilepsy patients. Seizure-controlled epilepsy patients usually average 1-1.33 polyclinic visits per year with frequency of visits every 9-12 months. Refractory epilepsy patients usually average 3-4 polyclinic visits per year with frequency varying between 3-4 months.

Neurologists make treatment decisions based upon what they learn from the patients themselves, and/or their caregivers, and also information collected via the epilepsy nurses. After the decision is made to do an intervention, follow-up phone consultations are scheduled with a nurse. Usually the scheduled phone consultations are made every four weeks during the intervention follow-up phase usually lasting 3-6 months. These scheduled phone consultations typically have durations of 30 minutes per call per patient.

Only some patients keep a hand-written seizure diary, which is presented during the visits to the polyclinic. In the epilepsy treatment chain, the phone calls (both scheduled and unscheduled) are the main way of reporting seizures, and these calls are usually made by the epilepsy patients themselves or in some cases by their caregivers. Therefore, the patients need to make time to call the polyclinic during their work day during the polyclinic's phone consultation hours. These unscheduled phone consultations typically have durations of 30 minutes per call per patient. The epilepsy polyclinic typically receives 2-10 unscheduled phone consultations per day, averaging to 5-6 unscheduled phone consultations per day and 100 unscheduled phone consultations per month. At present, the nurse must manage 50 hours per month of unscheduled phone consultations into their regular schedules.





## Pilot Rationale & Schedule

### Piloting a New Solution for Epilepsy Patient Treatment Chain Management

SOENIA<sup>®</sup> Suite offers a novel solution to provide standardized clinical data and to save time for the Epilepsy Polyclinic. SOENIA<sup>®</sup> Suite includes the SOENIA<sup>®</sup> Medical Diary (previously called SOENIA<sup>™</sup> Epilepsy Diary) and SOENIA<sup>®</sup> Cloud (previously called SOENIA<sup>™</sup> Epilepsy Cloud) as complementary products to offer a solution for reducing the number of scheduled and unscheduled phone consultations and also to reduce the amount of time needed for pre-scheduled phone consultation for epilepsy polyclinic patients. The solution modernizes the epilepsy patient treatment chain. The treatment chain is changed by patients providing the required information on seizures through a smartphone application, SOENIA<sup>®</sup> Medical Diary, which securely delivers the seizure information to a regulatory-compliant cloud based system, SOENIA<sup>®</sup> Cloud. The specialist nurse could then review the enrolled patient's seizures in nearly real time and schedule a contact if needed. Additionally, the aim for the neurologist is to make treatment decisions based upon this standardized data collection process when needed.

### Pilot Duration and Patient Base

The original pilot clinical trial was conducted from 05/2015 to 06/2016, which was followed up with a clinical trial end report. Fourteen patients participated in the original clinical trial.

The patient's age distribution ranged from 18 years to 80 years old. The original participants had simple and/or complex seizures, some had deep brain stimulation (DBS) treatment, comprising a group of autonomous and assisted care patients. All original pilot patients had severe/refractory epilepsy. Severe/refractory epilepsy means that at least two different drug treatments have been tested, which have not proven to be effective. The patients were also chosen from the group that had already undergone at least one video EEG recording after their diagnosis. Other excluding criteria were any other active neurological or psychiatric disorders besides epilepsy.

It is worth noting that the smartphone application was called SOENIA<sup>™</sup> Epilepsy Diary when the clinical trial was conducted, and the rebranded smartphone app called SOENIA<sup>®</sup> Medical Diary was released to the Apple App Store and Google Play Store during 05/2019. Therefore, the clinical study has been unaffected by the name change because all patients had the smart application installed before this time.



## Pilot Methodology

During the pilot the following steps were taken:

1. BrainCare Oy (BC) provided the original application pre-installed on Nexus 5 phones for each pilot patient, and after the initial pilot concluded BC provided a link for patients to download the smartphone application from the Apple App Store and Google Play Store.
2. During all scheduled patient visits, the nurse introduced SOENIA<sup>®</sup> Medical Diary to the patients. Installation and user instructions were included.
3. BrainCare Oy trained two staff members and enrolled them to the SOENIA<sup>®</sup> Cloud. Additional support was and is available at [support@braincare.fi](mailto:support@braincare.fi).
4. The nurse was advised to spend 0 to 30 minutes per week or every second week, reviewing online all of the enrolled patients. This time was made available through reduced and/or shortened phone consultations from patients asking about their situations.
5. The patients were originally provided Nexus 5 phones and then later asked to download and use the SOENIA<sup>®</sup> Medical Diary on their own phones after the original pilot so that their seizure history was available online to the Hospital Users (i.e., specialist nurse and neurologist) via the SOENIA<sup>®</sup> Cloud.
6. BrainCare Oy fulfilled all IT requirements to hold a patient registry during the pilot.
7. BrainCare Oy gathered feedback from the nurses throughout the Pilot Trial to learn about possible ways to improve the Service.

Therefore, the epilepsy treatment process documentation change during the clinical trial follow-up period expected the enrolled patients to have an Android or iOS phone. The patients that participated in the trial were capable and willing to use smart applications to document their seizures in a repeatable standardized way via the SOENIA<sup>®</sup> Medical Diary. The Hospital Users (i.e., specialist nurse and neurologist) monitored these pilot epilepsy patients through the SOENIA<sup>®</sup> Cloud.





## Pilot Results

The 48-month follow-up results are based upon the original fourteen patients from the clinical trial. From this 48-month period, over 12 146 seizures were digitally reported. After the completion of the original trial in 06/2016, the number of patients using the SOENIA<sup>®</sup> Medical Diary that are connected to the TaUH Neurology Epilepsy Polyclinic via the SOENIA<sup>®</sup> Cloud has increased to 39 patients.

### Improved Clinical Outcomes

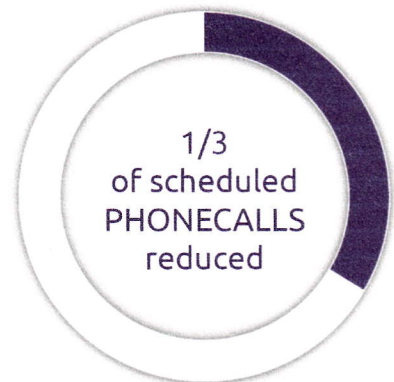
The results of the pilot included the following improved clinical outcomes:

1. There is **faster and better decision making** regarding each patient's individual care. The polyclinic can more quickly reduce patient adverse side effects and ineffective treatment cycle time over the course of the treatment. The polyclinic directly benefited from knowing what the status is of all the refractory patients in the pilot.
2. The polyclinic **improved its quality of care** by reducing the overall reaction time required to report a patient's adverse side effects because the SOENIA<sup>®</sup> Cloud provides real time seizure information reported by the patient. The overall reaction time is normally counted from when the patient consults the nurse to when the nurse consults with the neurologist on duty, which enables the polyclinic to **more quickly schedule an emergency visit if necessary** for epilepsy patients due to a recent treatment change. Faster reaction times typically translate to faster intervention feedback, which also reduces the risk of medical complications caused by the seizures.
3. There was **more detailed, accurate, and standardized** seizure reporting. The template seizure entry in the SOENIA<sup>®</sup> Medical Diary improved the overall quality of reporting across the pilot patients, especially for those that do not document well their seizure history such as type, triggers, location, time of day, etc. This is an improvement over the hand-written diaries because the nurse would usually provide only a summary overview in the medical records.
4. Reduced the errors in reporting -- missing and illegible diary entries were replaced by digital entries in the SOENIA<sup>®</sup> Cloud, which conveyed the diary entries as bar graphs, numeric seizure totals, and text of all reported seizures from each patient.

## Economic Savings through Saved Time

The time saved can be counted in multiple ways that benefit the polyclinic:

- The use of the SOENIA® Suite shortened the duration of scheduled and unscheduled phone consultations by up to 50%, typically reducing a 30 minute consultation to 15 minutes. While using the system the nurse does not have to interview the patient about their seizure history, because the nurse is able to see at a glance the seizures the patient has already entered into the system. In the current protocol the nurse is required to ask about the details of the seizures and then to document them into the hospital records, which may be done during or after the phone call.
- The nurse estimated that there were on average 2-3 scheduled phone consultations per week from the pilot patients that yielded approximately 30-45 minutes per week or 2-3 hours per month saved time from scheduled phone consultations.
- The nurse estimated that there was on average 1 less scheduled phone consultation per set of 3 scheduled calls per pilot patient that had a treatment change. Currently, there is no way to send a message through the SOENIA® Medical Diary to indicate that the call has been cancelled so a short phone call needs to be made. This is a suggested feature to implement and improve the Service. One less scheduled phone consultation saves 30 minutes, minus one short call to notify the patient about the eliminated call in total saving 25-29 minutes.
- Regarding the original patients enrolled in the system, the nurse estimated that the number of unscheduled phone consultations reduced by approximately 25% to 50%. Therefore, the nurse estimated that she saved on average at least 10 hours per month from a reduced number of unscheduled phone consultations just from the pilot patients.







5. The nurse reported that she saved about 15 minutes per office visit per pilot patient. This time was saved by eliminating the interview portion of the visit that is usually spent on counting or estimating the number of seizures each patient had since the previous encounter (either phone consultation or office visit). If there are on average 2 pilot patients (of the fourteen pilot patients) with office visits per month, then approximately 30 minutes can be saved during office visits per month.

In total, the monthly estimated time saved from the nurse is **8-12 hours per month** from the original 14 patients in the system and also estimated **at least 20 hours per month** for the current 39 patients using the system.

### Feedback from Patients

According to the specialist nurse, the patients, who use the SOENIA<sup>®</sup> Medical Diary (i.e., the Epilepsy Diary), prefer the smart application and are very satisfied with it. Patients detail the seizures very well in an informative way so usually there is no need to call for further information. The nurse indicated that compliance with the smart application is much better than the paper diaries because the paper diaries are typically forgotten.

### Quote from the Epilepsy Nurse

Epilepsy nurse Satu Hietala: *“Call times with patients are shorter and easier, because we can check the seizure inputs from the Epilepsy Cloud whenever they [the patients] want. Usually this leads to **patients being more motivated** to note down their seizures, which in turn **improves their adherence**.”*

*There is a lot of time saved in manual counting during clinic visits, because we can see the categorized seizure inputs from the cloud. The old pen and paper style does not motivate people, especially any of the younger patients.”*





## Conclusion

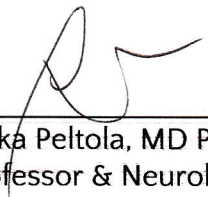
Based upon the improved clinical value and the time saved, Dr. Jukka Peltola, MD PhD recommends the SOENIA<sup>®</sup> Suite as an effective tool for epilepsy seizure management and recommends it to his national and international colleagues.


### Signatures:

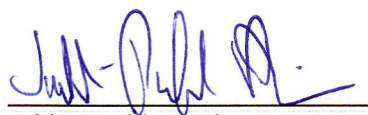
In Tampere on 15.5.2019

In Tampere on 15.5.2019

Pirkanmaan sairaanhoitopiirin kuntayhtymä BrainCare Oy

  
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Jukka Peltola, MD PhD  
Professor & Neurologist



  
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Katrina Wendel-Mitoraj, PhD  
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\_\_\_\_\_  
Jukka-Pekka Pirhonen, MSc  
CTO



## Appendix 1 – Signed Clinical Statement


The following two pages are the “Clinical Summary Report of Clinical Trial”, which is a statement signed by epilepsy specialist nurse Satu Hietala.

**BRAIN CARE OY (LTD.)**  
**CLINICAL SUMMARY REPORT OF CLINICAL TRIAL**  
 SOENIA™ Epilepsy Diary & Cloud

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SOENIA™ by BrainCare Oy, websites:  
 in English: [www.soenia.com](http://www.soenia.com),  
 Finnish: [www.soenia.fi](http://www.soenia.fi),  
 and Swedish: [www.soenia.fi/svenska.html](http://www.soenia.fi/svenska.html)

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**Clinical & Financial Benefits of SOENIA™ Epilepsy Diary & Cloud**

The original pilot was done in Tampere University Hospital between 6/2015 – 8/2016, with 14 continuous patients, some of which continued to use the system up to date.

Saved patient visits are a direct, clear benefit when patients can be tracked remotely. In addition, long-term cost benefits should be taken into account: easier monitoring of drug switching, side effects, increased effectiveness of treatment, greater motivation of patients for documenting their seizures and effective monitoring to avoid hospitalization. The tested device and its deployment responded well to the medical staff's and patients' wishes and no major problems or incidents occurred. The application and the cloud respond well to the challenges of the future, when the healthcare model is moving more and more towards an outpatient model.

**Clinical value**

1. More detailed, organized seizure data
2. Automated calculation helps with seeing a clearer, bigger picture
3. Faster and better decision making regarding each patient's individual care
4. The application proved to motivate the patients to document their seizures

**Cost-effective/economical value (Saved time values are estimates):**

1. Saved time in scheduled and unscheduled phone consultations between patients and the medical staff. About 50% of call times can be saved using SOENIA™, usually reducing call times from 30 minutes to 15 minutes.
2. Saved time on patient visits. 25-50% visits can be saved using SOENIA™.
3. Saves 90-100% of the healthcare professional's time through automatic logging compared to manually handling and documenting the seizure diaries.
4. Optimized remote monitoring gives a potential to increase the patient base.

**Signature**

*15.5.2018 Tampere Satu Hietala*

Date & Place: Satu Hietala, specialized epilepsy nurse  
 Tampere University Hospital, Neurology Polyclinic

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