Changing the Way That We See Multiple Sclerosis' Diagnosis and Treatment



### Challenge

Multiple Sclerosis (MS) is estimated to affect 2.5 million people worldwide, mostly in Europe and North America. MS represents a major public health issue with a large socioeconomic impact. In the majority of cases, over periods of 10-30 years, the disease leads to high-grade disability and death. The cause of MS remains unknown and there is no cure for MS. Due to the great variability in symptoms and disabling conditions experienced by MS patients, ongoing monitoring of physical, social, and cognitive/mental functioning is important to determine both appropriate counselling and treatment. However, with existing assessment tools, timely detection of disease progression is unreliable and leaves patients at great risk of irreversible disability. Current disease monitoring methods (clinical assessment, biological assessment, MRI assessments) are unreliable, complex and expensive, not providing the necessary scientific insights for treatment personalisation to ensure optimal outcomes and constituting an unnecessary waste of resources.

# **DIATOMIC** Support

Participating in the DIATOMIC project did two main things for us, it provided support through the coaches and keeped us focussed on the goals and timeline. Without the pressure the timelines would probably have slipped further and the discussions with coaches have given us ideas on how to solve a number of technical challenges.

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### Solution

DREAMS is a cost-efficient digital health platform. Through its remote patient monitoring and telehealth capabilities, it supports optimal clinical management of patients with MS. DREAMS uses data generated by the patient's mobile and wearable device sensor technology to track patient symptoms and disease progression. The data is translated into clinical assessment using a combination of proprietary and non-proprietary algorithms and presented onto a cloud-based dashboard for the treatment team. The information made available is equivalent to observational data that currently supports clinical decision-making in MS. DREAMS has 5 key components: 1. The mobile application for data capture; 2. Servers and databases for data storage and translating data into clinical insights; 3. A cloud-based dashboard and associated features to serve the clinical insights to the treatment team; 4. The telehealth platform; The interface (API) to connect the different components and allow integration with hospitals' Electronic Health Records.

#### Lessons Learned

The two main learnings from this Experiment were that it is important to get input and feedback from a wide range of stakeholders outside the Consortium early on and to be open to challenge assumptions and, to stay focussed on the key priorities, especially considering the complexity and opportunities that have emerged.

#### **TRL & Adopters**

TRL level at the beginning of the experiment: **6** TRL level at the end of the experiment: **7** Number of early/first adopters raised during the experiment: **0** 

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### Timeline

Showcase the research/business strategy and timeline of your actions taken, taken into account the three DIATOMIC phases: Design, Development, Market.

The DREAMS team has already secured significant early wins in obtaining interest from clinical experts and patient organisations, as well as scientific and industry partners. Their input and collaboration has confirmed the clinical and economic feasibility of the Experiment. However, they have also led to changes in the scope and complexity of the solution. To be ready for market introduction, we needed to improve scalability, user engagement and data processing. After a longer than estimated Development phase, the team is now delivering a better and better looking solution.

#### Stakeholders

The DREAMS Experiment is led by Healios with data scientists from the University of Cordoba (ES) and two neurologists at the IMIBIC research institute, linked to the University Hospital of Cordoba (ES), as collaboration partners. In the course of the Experiment we have worked with the MS patient organization in Cordoba, patient support groups, the department of Neurology at the University Hospital of Basel (CH), global pharmaceutical companies as well as a number of Biotech companies that are interested in using the platform for their own clinical studies.

#### End Users

Patients with MS and their HealthCare Professionals are the main targets for DREAMS. Health insurance companies and healthcare organizations will also benefit from a better monitoring solution at a lower cost. In addition, scientists, pharmaceutical companies and other biotech companies are interested in the capabilities for remote monitoring in the context of clinical studies.

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#### Key Results

The DREAMS Experiment has resulted in significant interest from clinical experts and patient organisations, as well as scientific and industry partners. The input has confirmed the clinical and economic feasibility of the Experiment and already secured income. MS patient organisations in Cordoba and Basel immediately showed interest in the solution and offered support in the ongoing development and improvement. Healios is in contact with two major pharma companies, through the RC2NB collaboration. The objective, in line with RC2NB's goal, is to form a trusted, independent platform for patients, neurologists, pharma companies and payers (insurance companies, health care systems). In addition, there are a number of biotech initiatives that have connected to discuss similar use cases for the DREAMS platform. Healios has also had a number of presentations to investor communities, including Digital Switzerland Start Up Day on May 28, 2019 and has obtained over CHF 0.5 million in funding during 2019. Additional discussions are ongoing.

#### Impact

There is broad attention for technology advances in the field of neurology and MS in particular. Healios has connected with one of the best known Key Opinion Leaders in MS, Professor L. Kappos of the University Hospital of Basel (USB). With USB, Healios has established a collaboration agreement that covers further development of the DREAMS app, including a regulatory longitudinal study to support filing of the DREAMS solution as a class II Medical Device Software (MDSW). COVID-19 pandemic has stressed the importance and opportunities of remote patient monitoring and study executing, further underlining the DREAMS benefits. USB has founded the "Research Centre for Clinical Neuroimmunology and Neuroscience Basel" (RC2NB). This institute has secured grants from the University as well as pharma corporations. The aim of the foundation is to promote and coordinate the activities of various researchers at the USB and the university as well as industry in the field of neuroimmunology and MS. Healios has a four-year collaboration agreement, including terms regarding IP and exploitation, with RC2NB. RC2NB is in discussion with at least four study centres for collaboration (NL, DE, GR, CH).

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### Testimonials

C The treatment teams simply do not have enough information to properly assess disease progression nor we can predict prognosis. What is needed is precise and continuous monitoring, such as DREAMS.

Prof. Eduardo Agüera, Hospital Universitario Reina Sofia
Córdoba, Spain

C DREAMS has the potential of a great innovation for MS research and clinical management. The aim is to change the way neurologists monitor and treat MS. Comprehensive and easily obtained monitoring will inform timely personalised treatment decisions.

Prof. Ludwig Kappos and team, Universitätsspital Basel,
Switzerland

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