Challenge PROGRESS

Pitch

Development and validation of a solution for the collection, analysis and monitoring of the daily activity of patients with Multiple Sclerosis.

Motivation and description

Multiple Sclerosis (MS) is an inflammatory neurodegenerative disease of the Central Nervous System that is the main cause of neurological disability in young adults. Its prevalence is 100 cases per 100,000 inhabitants, with an estimated three million cases in the world, more than 45,000 in Spain and more than 1,500 in the Region of Murcia.

In 85% of cases MS manifests in a relapsing/remitting form (rRMS) and in 15% in a primary progressive form. Over the years, rRMS progresses to a secondary progressive form (SPMS) that progressively incapacitates the patient. The disability manifests itself in impairment of gait, cognition, manual dexterity and vision. This progression (PEM) begins to be seen in a more overlapping manner from the early stages of MSrr, undetected by current assessment methods. Fatigue is a frequent and very limiting symptom of the disease in daily activities. Measurements of gait speed and manual dexterity are part of the ways of monitoring MS

The usual way of detecting progression is periodic review every 3 to 6 months - for 30 minutes with a neurologist and 20 minutes with a nurse - consisting of questions and neurological examination using different types of standardised tests. With this usual screening method, it has been estimated that there is a delay of 3 years in the detection of progression, with only 33% of cases being diagnosed[1].

Patients and neurologists need a faster and more sensitive way to detect MS progression so that treatment can be started as early as possible to avoid disability. Faster and more sensitive detection of progression would also shorten treatment evaluation times in clinical trials in collaboration with the pharmaceutical industry.

Main objective

The **main objective** is to create and validate a more agile, comfortable and sensitive solution for the detection of progression in MS based on the daily recording of gait disturbances, manual dexterity and cognitive assessment, and the relationship of the latter with fatigue and mood.

As an intermediate result we would have the following **secondary objectives**:

1. Detection of possible **outbreaks** of the disease (worsening of gait and/or usual activities lasting more than 24 hours). These would be episodes not reported by the patient as such but reflected in the measured parameter.

[1] https://pubmed.ncbi.nlm.nih.gov/30851128/

2. Detection of **treatable symptoms** that interfere with the patient's daily life (depression, anxiety, sleep, fatigue).
3. Detection of **progressive deterioration** throughout the observation period. Worsening in measured parameters, especially gait. Consideration should be given to improving treatment.
4. Improved **quality of life** by being able to better treat the patient's symptoms, as reflected in the quality of life scales of the patients included in the pilot before and after the intervention.
5. Less **trips** to the hospital and more specific consultations.
6. Decrease in the incidence of **disability**, if MS progressions are detected more sensitively or earlier than the standard method.

Pilot functional scope

An objective and quantifiable assessment of disability and a channel of communication of this information between the patient, his or her neurologist and the health care system is needed to generate a rapid and effective treatment response. This would benefit all MS patients at all stages of the disease.

The total duration of the pilot (development + test) will be 10 months. The minimum sample required to be able to draw conclusions will be **30 patients** with moderate affectation and without physical limitations. The 30 patients included in the project will be assessed at the beginning and end of the study by a Neuro-immunology Unit of the Murcian Health Service (SMS). **The solution will have to record** the data -specified in the following paragraph - of the 30 patients **continuously and simultaneously during the 150 days** (5 months) of the study

Throughout the pilot period each patient must complete the fatigue and depression/anxiety **tests** on a **weekly** basis and the quality of life tests on **a monthly** basis

The solution provided by the company will allow the following data to be recorded on a **daily** basis:

- Walking:
  - Steps (number, length, duration, cadence).
  - Distance, duration and average speed of sections travelled and daily totals.
  - Turns (number, amplitude, average speed)
- Wrist movements (number, amplitude and duration)) distinguishing running and static periods.
- Fall detection.
- Heart rate.
- Sleep:
- Duration.
- Start/end time.

Analysis of results:

1. Review and visualisation of historical data and extraction of daily, weekly, monthly averages.

2. Check the significance of the slope of the regression line of the recorded data if it is negative and significant (it would be two-tailed).
3. And finally to perform statistical analysis of the association of the data recorded with the monitoring, with the clinical data and the tests carried out on the patients.

Necessary requirements:

The successful candidate shall be responsible for the automated patient data recording service. This service includes the delivery, training, repair, replacement, collection, maintenance and support of the devices, ensuring their availability. The replacement of a device that has problems collecting or downloading data to the analysis system shall be carried out within a maximum of 24 hours. Losses of logging service shall be accounted for in the service level compliance indicator explained in the section below

The **mandatory** requirements are:

1. DIGITAL ACTIGRAPH: Data recording MUST be carried out by a SINGLE DEVICE internally equipped with the necessary sensors, which is robust (operating 24/7 during the 150-day duration of the pilot), waterproof (daily cleaning), lightweight (<100 g) and small in size (bracelet, watch, etc.) requiring minimal intervention by patients and no expendable items associated with its use. The device's autonomy MUST allow data logging on a single daily battery charge (<4 hours) using a system that is as simple as possible and does not require manual dexterity.

2. DOMESTIC GATEWAY: The data recorded by the device MUST be stored daily in the cloud during the charging of the device through its wireless connection (Bluetooth / WiFi / Other) with the domestic gateway to be provided by the company without requiring any intervention by the user or the prior existence of internet access infrastructure at home. In the event that the device has its own 4G / 5G connectivity, this requirement will be optional and the company will be responsible for the connection costs

3. CLOUD APPLICATION: Application to be run on external servers to receive the data recorded by the actigrapher for storage in the cloud and provide access to it from the different display modules.

4. CLOUD STORAGE: Data (patients, users, access, etc.) will be stored on secure servers that ensure general data protection compliance (2016/679). Both the storage space and the cloud processing capacity required for data recording and processing MUST be provided by the company as part of its solution.

5. INFORMATION ACCESS AND VIEWING MODULES: The cloud application will receive the request to access and view the information stored in the database from the access modules for each user.

a. The **clinical** visualisation and access module allows the visualisation of recorded data, clinical, rehabilitation and daily, weekly and monthly activity reports for each patient and the incorporation of diagnostic test results by physicians. Several clinicians can be assigned to each patient in order to allow access by specialists and primary care.
b. The **therapeutic** access and visualisation module allows the visualisation of recorded data, rehabilitation reports, daily, weekly and monthly activity reports for each patient and the incorporation of the assessment of therapeutic actions by the rehabilitators assigned to each patient.
c. The **patient** access and visualisation module allows access to weekly and monthly summaries of patient activity. It allows the incorporation of answers to clinical assessment questionnaires (scales of fatigue, depression/anxiety, cognition, quality of life, satisfaction with the system) and rehabilitation questionnaires.

The exploitation and visualisation of the recorded data, as well as the remote maintenance of the different elements of the system MUST be carried out through web interfaces that allow multi-platform exploitation..

6. MANAGEMENT AND MAINTENANCE MODULE: A web/app module is to be provided to allow management and storage of the hardware/software elements of the system.

Optional requirements
The following aspects shall be positively assessed:
- Presentation of the walking data by sections (short, medium and long). (+10 points)
- Distance to home (by comparing geolocation with the patient's registered home) (+20 points).
- Location of patients within the different rooms of the home. (+20 points)
- Wrist movements (number, amplitude, duration, modulus and xyz angles of orientation, speed and acceleration) distinguishing walking and static periods (+20 points).
- Presentation of heart rate data according to the intensity of the activity performed (low, medium, high) identifying event number, duration, start and end times. (+10 points)
- Labelling of sleep periods according to sleep phase/depth and/or quality of sleep. (+10 points)
- Device internal memory in days of recording (+20 at maximum capacity, +10 if equal or above average).
- Battery life under normal operating conditions with sensors active 24/7 and a single daily synchronisation of data (+20 at maximum duration +10 at equal or above average duration).
- Recharge time required for full charge (+20 to minimum time +10 to below or equal to average time).
- Raw recording of data obtained from the device's sensors. (+2 for each variable, +5 if it also has the best sampling rate).
- CE marked medical device (+20 points)
- Proprietary 4G/5G connectivity (+20 points)
- Other functionalities: Possibility to mark events, add voice notes, launch emergency messages, etc. (up to +20 points)

Expected impact and KPIs

Health outcomes:

- Indicator: increase of **detected progressions**
  - Objective: detection of 3 MS progressions among the 30 patients during the 5 months, not detected by the usual clinical method.
- **Quality of life** before / after valued through the SF12 short questionnaire. Goal: 20% improvement.

Satisfaction:

- Tool **satisfaction** survey segmented by user roles (patient, neurologist and nurse) using *the Customer Satisfaction Score* (CSAT).*):*
  - Goal: CSAT >8 (out of 10*) in each user group (role).*
- *Patient **experience** through the Net Promoter Score (NPS):*
  - Goal: NPS >+50
- **Usabilidad** por el paciente medida a través del *System Usabilidad Scale (SUS).*
  - Goal: SUS >80
- **Level of service:** Registration service losses will be counted as number of days/patient without service (30 patients x 150 days = 4500 days/patient) and should be less than 1% (= less than 45 days/patient without service)).

Clinical and Ethical and Data Protection

The Entity undertakes to process the personal data to which it has access as a result of the execution of the contract, observing the principles required by the legislation on data protection, in particular those relating to data quality, data security and duty of secrecy, as well as in accordance with the specific instructions received from the data controller, not using the data for any purpose other than the provision of services described in the object of the contract. Likewise, it undertakes to observe professional secrecy, maintaining absolute confidentiality and confidentiality on any data it may come to know on the occasion of compliance with the contract, in accordance with the level of protection established in the European data protection Regulation (EU 2016/679)of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data and Organic Law 3/2018 of 5 December, on the Protection of Personal Data and guarantee of digital rights, not communicating to any third party the data provided by the data controller. The data controller will determine whether, at the end of the services provided by the data processor, the personal data should be destroyed, returned to the data controller or handed over, where appropriate, to a new data processor. The destruction of the data shall not proceed when there is a legal provision obliging their conservation, in which case they shall be returned to the data controller, who shall guarantee their conservation for as long as such obligation persists. This obligation will continue even after the end of their relationship with the person in charge. The Entity will ensure and be responsible for its employees and / or collaborators receive the data only to the extent that it is necessary to their knowledge for the provision of the object of the contract. In the event that the Entity uses the data for purposes other than those stipulated, communicates them or uses them in breach of the instructions set out in this contract, it shall be liable for the infringements set out in Articles 70 et seq. of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, in which it has incurred.

Technological

The user identification will be then provided through the OAuth standard. The solution may notify SMS systems about certain events and situations. Ideally via ´HL7´ messaging, but web services could also be an option. This information may include registration status, activity, progress and periodic (summarized) clinical information. The IT systems needed for running the solution will be hosted by the solver. If the complexity of the connections is too high or the personal data could be at risk, these systems could be hosted in local servers of the SMS. This will be established in a technical session at the beginning of the project. Anyway, the solver will provide mechanisms to guarantee that the Servicio Murciano de Salud can exploit the data. Data No prior Challenger data is expected to be available, meaning all users will start as new users in the system. The repository of documents and resources to be shared with the end users will be supplied and / or validated by the SMS.

Business opportunity

In our Region the number of patients with MS exceeds 1500 and at national level more than 45,000. The variables considered are applicable to any progressive degenerative neurological disease, above all with gait impairment, such as Parkinson's disease (at regional level some 3500 patients with MS).

Offer of cooperation from the challenger group:

1. Advice on business model.
2. In case of success of the pilot experience, the SMS undertakes to manage the possible resulting solutions in the volume to be determined, through the appropriate legal means, in particular as provided by the contractual regulations.
3. Dissemination of results with the support of clinicians and patient associations through the networks of the 43 Multiple Sclerosis Spain entities and in the LinkEM Annual Conference Knowing, Connecting and Innovating in Multiple Sclerosis, in order to make patient organizations aware of the solution at national and international level.
4. Collaboration with a study of cost saving based on the published evidence2, as well as with its publication and dissemination.
5. Identification and contact with other potential customers.
6. Advice on collaboration with the pharmaceutical industry by shortening treatment evaluation times in collaborative clinical trials.
7. The company will receive free assistance to promote the solution internationally through the Enterprise Europe Network of the EU, in order to look for possible business opportunities in other countries.
8. The company will receive free guidance on the actions it should take for the industrial/intellectual protection of the project results.

[2] https://pubmed.ncbi.nlm.nih.gov/27411042/
https://pubmed.ncbi.nlm.nih.gov/31285832/
https://pubmed.ncbi.nlm.nih.gov/31848738/
https://journals.sagepub.com/doi/full/10.1177/1352458517708141