General information about the project

Title of the project: Identifying Digital Endpoints to Assess Fatigue, Sleep and Activities of Daily Living in Neurodegenerative Disorders and Immune-mediated Inflammatory Diseases. IDEA-FAST

Aim of the project: IDEA-FAST aims to identify digital endpoints that provide reliable, objective and sensitive evaluation of activities of daily life, disability and health related-quality of life for the following neurodegenerative diseases: Parkinson's Disease, Huntington's Disease and the following immune-mediated inflammatory diseases: Rheumatoid Arthritis, Systemic Lupus Erythematosus, Primary Sjögren's Syndrome, Inflammatory Bowel Disease.

Dates: November 2019 – April 2025

Funded by: IMI2 project under Call H2020-JTI-IMI2-2018-15-two-stage – digital endpoints in neurodegenerative and immune-mediated diseases

Countries involved: 15 countries in Europe

Partners in the consortium a consortium of 46 partners across 15 countries in Europe.

Budget: total budget €42 Million

About Public Involvement activities

- **Who was responsible for the Public Involvement activities?**

Our Patient and Public Involvement and Engagement (PPIE) activities are coordinated by the Work Package 2 (WP2) [Clinical Knowledge and Insight] partners. During the first month of our project, we held a planning meeting in Kiel, Germany and a Clinical Knowledge and Insight Task Force (CKI-TF) was established which provides an oversight for the PPIE strategy and implementation. The CKI-TF includes individual patient partners representing different diseases, patient organisation partners of the IDEA-FAST consortium, clinicians, scientists as well as legal and regulatory experts.

- **What Public Involvement activities were carried out, when, what the activity/ies consisted of?**

In IDEA-FAST, a range of different PPIE activities has been carried out. To organize these different activities, we have formed two groups.

The Patient Involvement and Engagement Group (PIE Group) consists of patients, members of patient organisations, researchers and a broad range of consortium partners. The aim of the PIE group is to facilitate a broad discussion on PPIE strategy and issues among consortium partners and external organisations (e.g. Lupus UK, European Huntington's Association). They are involved in all aspects of the study. They meet monthly to give updates on the study and discuss issues that require public input or plan and discuss further PI activities. Their activities include:

- Involvement in the planning of the Clinical Observation Study, such as decisions how questionnaires should be delivered, discussions about the use of different apps or the need for GP Letters
- Planning of two focus groups with members of the PSAB and participants of the Feasibility Study

- Planning of a patient survey and distribution through the patient organisations
- Planning of a patient engagement workshop

The Patient Specialist Advisory Board (PSAB) consists of seven patient experts from our target diseases. They provide strategic advice to the consortium at multiple levels and the group is a formal advisory body within the governance structure of the IDEA-FAST consortium. There is a formal Confidential Disclosure Agreement in place between the PSAB members and the consortium. The PSAB also helps with important, specific tasks. Examples of these activities include:

- Testing devices to be included the Feasibility Study and giving detailed feedback on acceptability and usability
- proofreading all patient-facing materials such as patient information to ensure readability
- taking part in a focus group to discuss questions for the Clinical Observation Study
- Participate in our Feature Engineering Exercise to help identify candidate digital features of fatigue and sleep
- Participate in different WP activities, e.g. the discussion of data privacy, and drafting of the model informed consent document organised by WP8, and our engagement with the EMA at the Innovation Task Force meeting in October 2020.

PPIE activities are embedded within project activities/clinical studies. For example, we have conducted a digital technology workshop, providing hands-on experience for patients and consortium partners to try out the digital devices. During the Feasibility Study, we have collected feedbacks from participants on their experience of using digital technology, as well as an optional qualitative sub-study to understand the overall experience of the research participants on the study as a whole.

General dissemination is coordinated by WP9 “Dissemination, Impact, Exploitation & Sustainability”. To date, PPIE related activities are mainly carried out via our project website and twitter account, as well as presentations in meetings of patient organisations.

- **Was it a “one-off” or an ongoing involvement?**

All the above strategy will be maintained throughout the entire project. The PIE Group meets regularly. The PSAB meets when specific activities are required but they are also invited to our annual general assembly and quarterly steering committee meetings where appropriate. We plan to embed PPIE activities within our Clinical Observational Study, and we will continue to expand on our general dissemination activities. Most tasks are, however, one-off. The groups take on new tasks and plan activities throughout their engagement.

- **Who was involved in the Public Involvement activities?**

Different groups are involved. The PSAB consists of patients from the target diseases. Some of these members also take part in the PIE Group. Here, they meet with researchers from the project and representatives from patient organisations such as Parkinson’s UK, European Federation of Crohn’s and Ulcerative Colitis and Asociación Parkinson Madrid as well as representatives from industry partners. It also includes external patient organisations such as Lupus UK and European Huntington’s Association.

- **How was the input of the Public Involvement activities used?**

Input from the patient specialists has been used directly to inform different aspects of our project such as to improve our patient-facing materials, to incorporate patient feedback in the protocol of the Feasibility Study and Clinical Observation Study. As an example, members of the PIE Group discussed the distribution of a weekly questionnaire during the Clinical Observation Study. They talked about different options and their preferred option was chosen to use in the study. Moreover, opinions of patients contributed decisively to the selection of devices to be used in the Clinical Observation Study.

- **Is it there any information in the public domain about the Public Involvement activities?**

On our website, idea-fast.eu, information on our PSAB members can be found. However, we are planning to update our website to include more information about our PPIE activities!

- **Any other relevant details about the Public Involvement activities:**

In 2022, we are planning to explore the use of a digital platform (VOICE) to conduct some of our PPIE activities.