



IDEA FAST **Mid-term Achievements Report**

Identifying Digital Endpoints to Assess Fatigue,
Sleep and Activities of Daily Living in
Neurodegenerative Disorders and Immune-
mediated Inflammatory Diseases

May 2023



innovative
medicines
initiative



Foreword

We would like to say a big thank you to all IDEA-FAST partners for their contribution and dedication to the IDEA-FAST project. Although the Covid-19 pandemic has eased, its impact on the entire research ecosystem remains considerable, posing challenges to the planning and delivery of our project activities. Nevertheless, we have risen to the challenges and made good progress towards achieving our objectives. This could not have been done without the hard work, collaboration and effective working across different Work Packages and consortium partners. We would like to take this opportunity to highlight some of our key achievements up to May 2023.

Following the completion of the Feasibility Study (FS) and sleep sub-study in 2021, we have completed the FS primary data analysis and are pleased to observe that there is a high level of interest and support among our patient participants to assess and monitor their fatigue and sleep using digital technology, confirming our patient centric approach.

We have co-developed the Clinical Observation Study (COS) protocol with our patient partners, who have contributed to all aspects of its development, such as device selection, study design and study documentation preparation.

We are particularly pleased to have received overall support from the European Medicines Agency (EMA) Scientific Advice Working Party (SAWP) on our study design and data analytic plan.

In preparation for the COS delivery, we have developed three data management platforms

to support the delivery of the COS which include the IDEA-FAST Data Management Platform (DMP), the COS Clinical Database and the IDEA-FAST Dashboard - an integrated platform to support study delivery staff.

We are also delighted to be able to maintain a high level of engagement with our patient partners through our Patient Specialist Advisory Board (PSAB), the Patient Involvement and Engagement (PIE) Group, patient organization partners as well as other engagement activities such as focus groups, online surveys, webinars and meetings with local patient support groups.

Finally, we are also looking forward to two new industry partners, Bristol Myers Squibb and Sage Therapeutics, joining our consortium in the next reporting period.

Many thanks to all IDEA-FAST partners who have made all this possible!

Yours sincerely,

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IDEA-FAST Coordinator

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About IDEA-FAST

IDEA-FAST is a 5½-year project that aims to **Identify Digital Endpoints to Assess Fatigue, Sleep and Activities of Daily Living in Neurodegenerative Disorders and Immune mediated Inflammatory Diseases.**

It is run by a consortium of 46 partners across 15 countries in Europe and the USA.

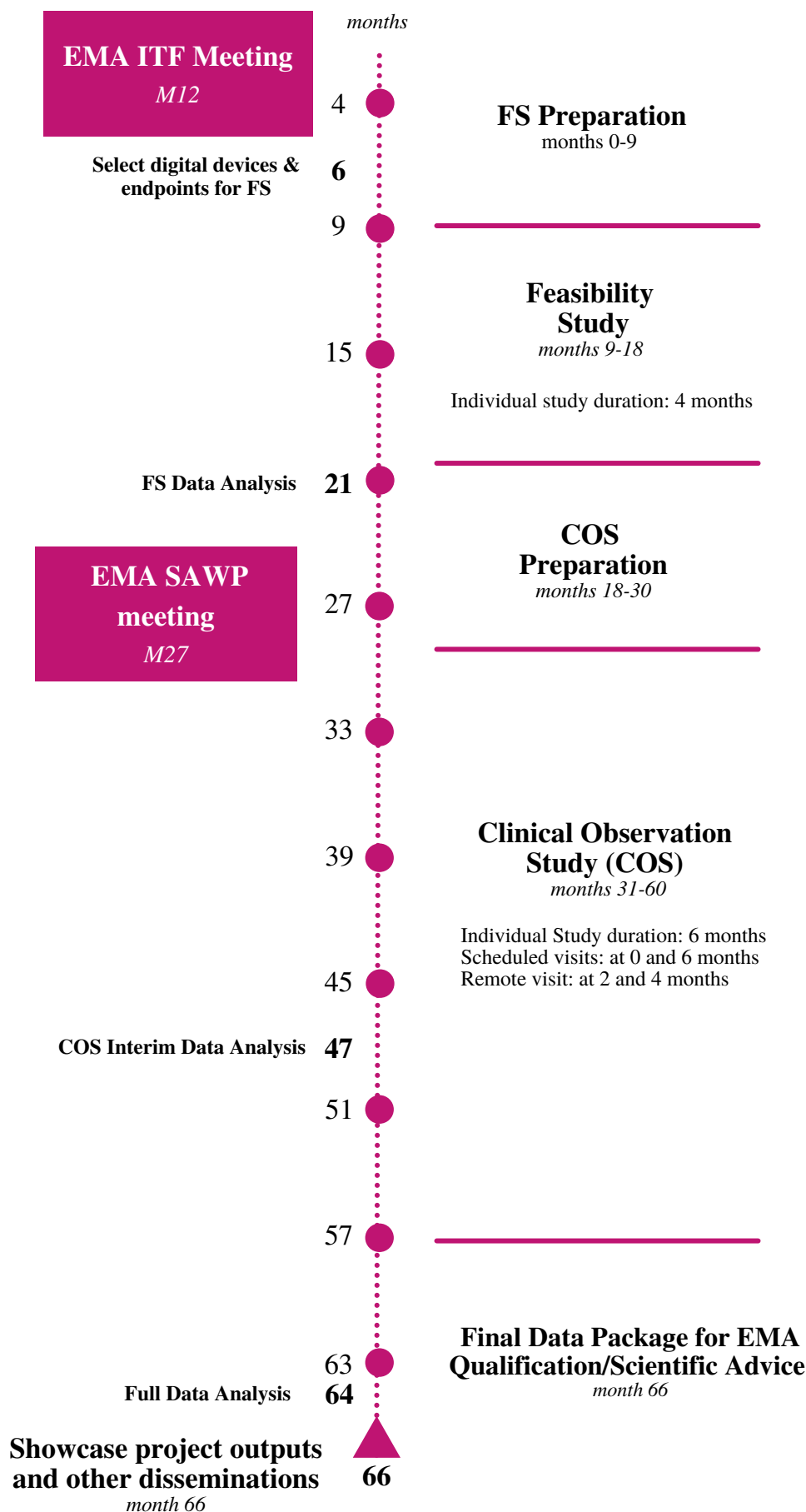
IDEA-FAST has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853981. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation program, EFPIA and PARKINSON'S UK.

The project aims to:

1. Define digital endpoints for the assessment of fatigue and sleep problems, as well as to investigate digital correlates of selected ADLs in patients with Immune Mediated Inflammatory Diseases (IMIDs) and Neurodegenerative Diseases (NDDs) and seek scientific /qualification advice from the EMA and/or FDA on such digital endpoints.
2. Ensure long-term impact by developing a large, real-world digital dataset of biophysiological, neurocognitive, personal, environmental, behavioural and socialization observations, along with comprehensive clinical data and data analytics to support future research and drug development.



Project Timeline



IDEA-FAST Disease Cohorts

Parkinson's Disease (PD)

Parkinson's Disease (PD), the second most common neurodegenerative disease, results from the loss of dopaminergic neurons. It is clinically characterised by an array of motor symptoms: resting tremor, face and muscle rigidity, bradykinesia, and postural instability, as well as autonomic, cognitive, and psychiatric problems. Although the disease progresses slowly, it is irreversible, and there is still no treatment to cure the condition or halt its progress.

Systemic Lupus Erythematosus (SLE)

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease in which the immune system mistakenly attacks the body's own healthy tissue, leading to inflammation and tissue damage. It can affect different parts of the body including the joints, kidneys, lungs, brain, and blood vessels. There's currently no cure, but some medicines and lifestyle adaptations can help control the condition.

Primary Sjögren's syndrome (PSS)

Primary Sjögren's Syndrome (PSS) is a systemic autoimmune condition damaging the tear and salivary glands. It is characterised by symptoms such as dry eyes and mouth, but often also includes blurry vision, dry itchy skin, tooth decay, an abnormal sense of taste, fatigue, and more. It can also affect other parts of the body including the skin, joints, lungs, kidneys and the nervous system.

Huntington's Disease (HD)

Huntington's Disease (HD) is a rare neurodegenerative disease associated with abnormalities in the Huntington gene, causing a dysregulation in gene expression. The disease is characterised by motor, psychiatric and cognitive disturbances. The presence of hypokinesia and hyperkinesia makes daily activities increasingly more difficult, and all muscles are affected. Cognitive decline, apathy, and increased anxiety are also common symptoms.

Inflammatory Bowel Disease (IBD)

Inflammatory Bowel Disease (IBD) are conditions characterised by a chronic inflammation of digestive tract tissue, which can range from mild to life-threatening. It can also manifest through a variety of symptoms such as diarrhoea, fatigue, abdominal pain, weight loss, and more. There are two main types of IBD: Ulcerative Colitis, characterised by ulcers along the large intestine, and Crohn's Disease, which most commonly affects the small intestine and causes deep inflammation.

Rheumatoid Arthritis (RA)

Rheumatoid Arthritis (RA) is an autoimmune inflammatory condition which mainly attacks the joints. It causes chronic pain, stiffness, deformity, and swelling in the joints, as well as fatigue, weakness, and weight loss. It can also affect other tissues in the body such as the lungs, heart, and eyes.

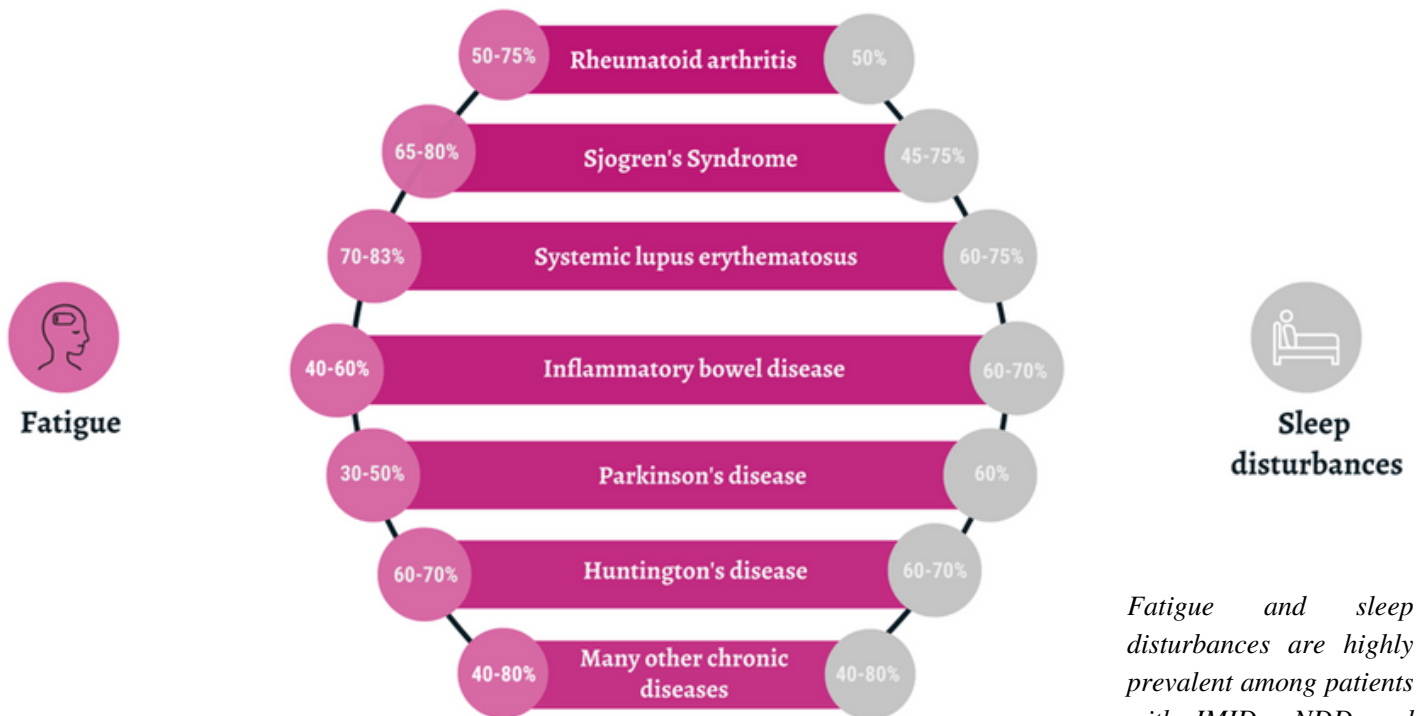
Fatigue and sleep disturbances - major burdens for society

DESPITE being highly prevalent in our society, symptoms of fatigue and sleep disturbances remain difficult to treat, measure, and to conceptualise.

Fatigue is a multi-faceted phenomenon which includes physical, cognitive, motivational, and emotional aspects while being highly unpredictable and variable in its presentation. Fatigue, specifically physical fatigue, can be expressed as people's inability to start, continue, or complete activities of daily living while having a consistently low level of energy.

Mental fatigue also relates to the inability to “recharge or energise” and often presents itself as the inability to concentrate or remember events and specific details; leaving patients in a state that they describe as “mental or brain fog”.

Similarly variable, sleep disturbances encompass many disorders across the spectrum, including disorders initiating and maintaining sleep, specific disorders of the sleep-wake cycle, and non-specific dysfunctions associated with sleep.

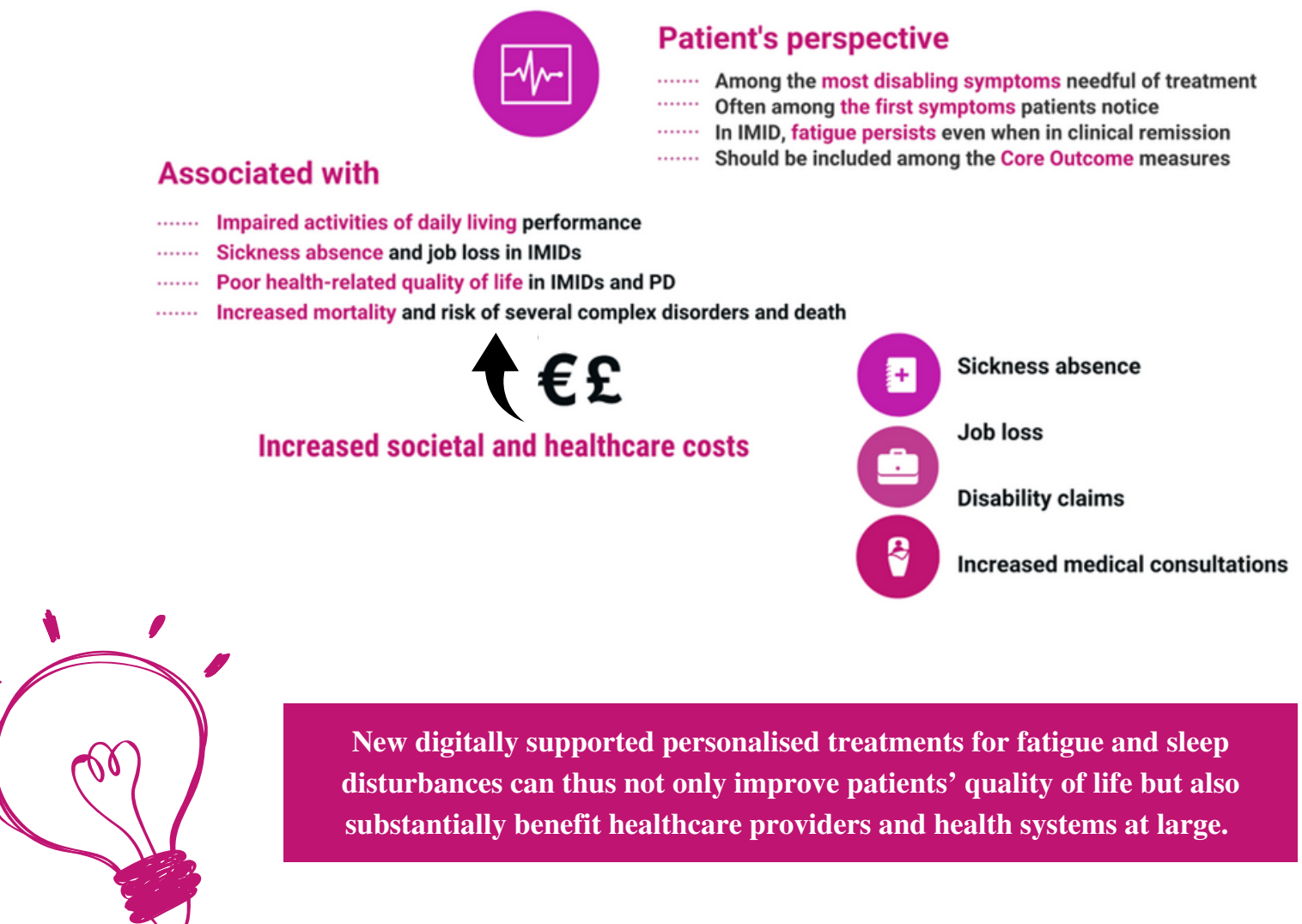


Fatigue and sleep disturbances are highly prevalent among patients with IMIDs, NDD and many chronic diseases

Fatigue and sleep disturbances are highly prevalent as symptoms of many diseases including both neurodegenerative (NDDs) and immune-mediated inflammatory (IMIDs) diseases. They remain poorly understood and, with no current specific treatment to address them, contribute significantly to alterations in patients' Activities of Daily Living (ADL) and Health Related Quality of Life (HRQoL), worsening other symptoms of the illness. For example, in patients with Huntington's Disease, depression and cognitive impairment, debilitating symptoms by themselves, are also associated with alterations in sleep and circadian rhythms.

Research shows that a lack of sleep leads to increased mortality risk, lower productivity, and impaired quality of life. Patients with fatigue also consume more healthcare resources than their counterparts without fatigue. Lack of sleep, or low-quality sleep, negatively affects physical and mental health, increasing societal and healthcare costs across the board. Furthermore, clinical trials to develop new therapies for treating fatigue and sleep disorders can cost between 800 million to 2 billion dollars and require 10 to 15 years to complete all phases.

Fatigue and sleep disturbances



IDEA-FAST is identifying digital endpoints through the Feasibility Study and the Clinical Observation Study

DIGITAL technology and digital endpoints may provide a novel way to measure fatigue and sleep disturbances more accurately.

Endpoints refer to direct markers used to assess health and disease which requires a set of criteria to define health status and progression, and the digital aspect is characterized by the use of sensor-generated data collected in the patient's everyday environment. Identifying accurate and reliable digital endpoint technologies will lead to regulatory recognition of digital mobility assessment as a critical secondary or primary endpoint for clinical trials, facilitating both digital assessment and drug development to progress.

"Why could this be interesting for you, the interested reader? Well, would it not be wonderful if you could soon keep a "fatigue diary", which you could perhaps fill in a little bit yourself but which is passively written by allowing your smartphone or smartwatch to observe your mobility, your reactivity, your interaction with friends? As I write this, I can think of the reasons why it might not be so attractive: can someone else watch me? Is the data secure? Do I even want to know it? These are all questions that need to be considered when thinking about the use of digital technology."

"The fact is that we are entering a new era of medical diagnostics and therapy, and that this brings with it a new dimension for all of us: Patients can actively participate in diagnostics and therapy. But for this they need information: information that only they have, and not the doctor. The smart thing is that they can either keep it with them or share it with the doctor – or with the physiotherapists, the self-help group, whatever they think makes sense. This is what IDEA-FAST stands for: The project wants to capture a really annoying symptom that many people have in a completely new dimension of accuracy and granularity. This will be achieved with new technology that can be used at home. It is our dedicated aim that the knowledge is then primarily to be made available to those affected."

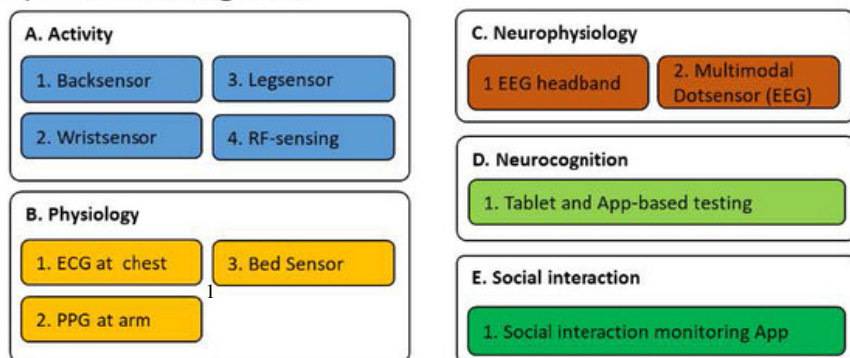
Walter Maetzler,
IDEA-FAST Co-coordinator

To develop digital endpoints that address fatigue and sleep disturbances, IDEA-FAST adopted the Clinical Trials Transformation Initiative approach, and consequently defined several concepts of interest (COIs), that stand for characteristics impacted by fatigue and sleep disturbances.

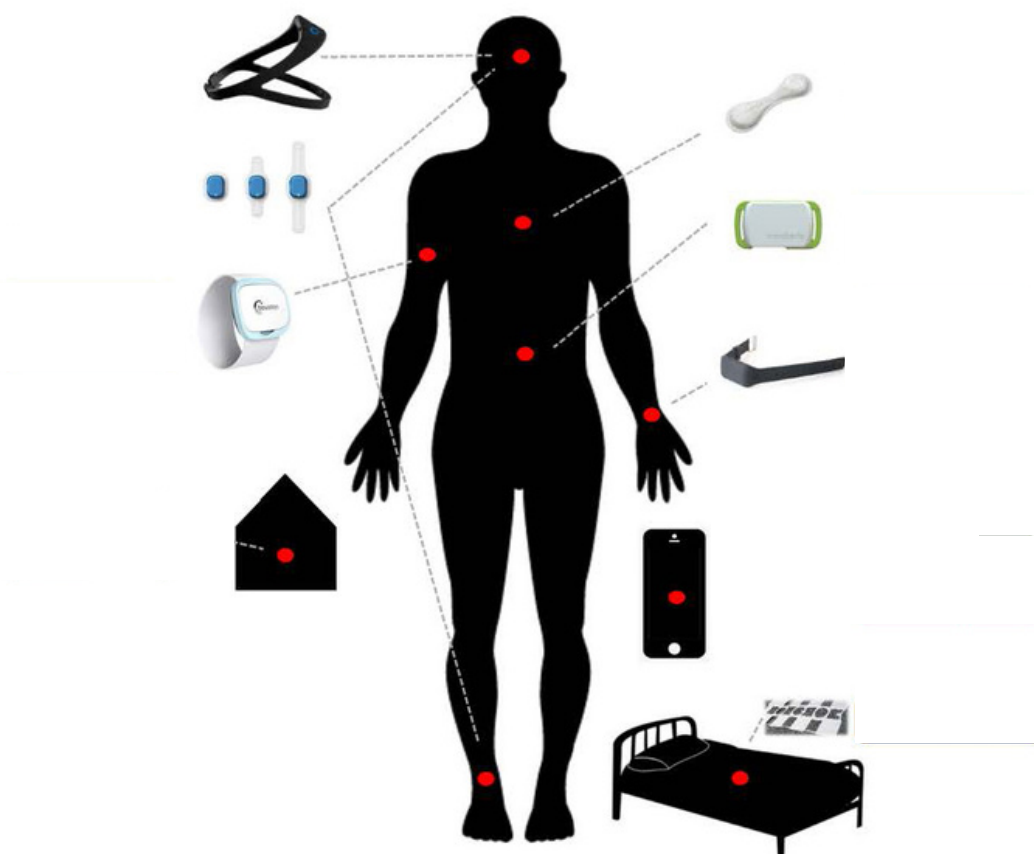
The COIs pertain to the following five domains: 1) physical activity, 2) physiology, 3) neurophysiology, 4) neurocognition, 5) social function and interaction.

Further, examples of candidate digital endpoints to assess these dimensions of impact of fatigue and sleep disturbances were proposed. Each COI was operationalised and mapped to digital devices and technologies.

a) Device categories



b) Device locations

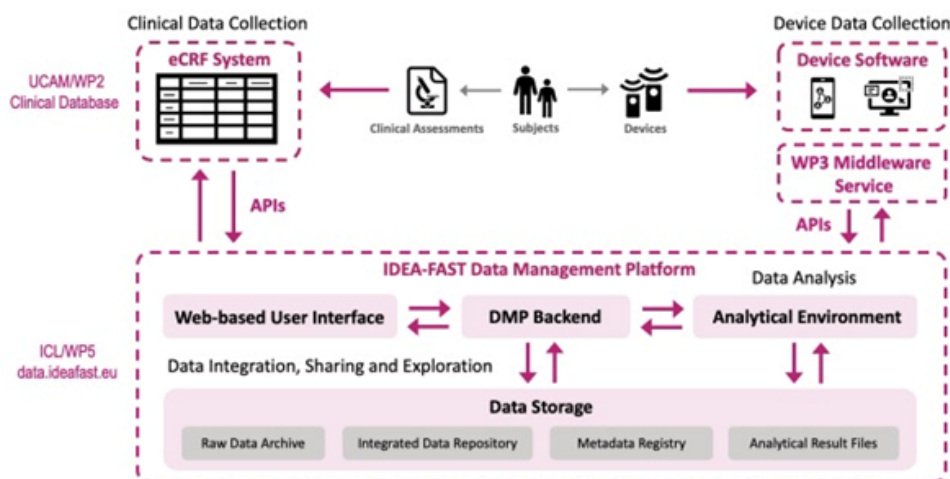


Device categories (a) and the actual devices and their locations (b) utilised in the IDEA-FAST feasibility study. Source: D4.1 Definition of Assessment Protocol.

Data Management Platform and Analysis

IDEA-FAST's goal of identifying digital endpoints for fatigue and sleep disturbances is, at its root, supported by data. Multimodal data on measures of fatigue, sleep, and selected activities of daily living are collected through the project's studies. The IDEA-FAST Data Management Platform (DMP) is a shared work environment enabling the curation, validation, and integration of underlying datasets while

adhering to strict standards for security and privacy. Led by the Imperial College London, the IDEA-FAST DMP is designed to meet the FAIR (Findable, Accessible, Interoperable, and Reusable) Guiding Principles for scientific data management and stewardship and be fully compliant with the EU General Data Protection Regulation (GDPR) Legislation.



The DMP analytical environment allows users to work with the project's datasets without needing them to download a local copy. The following types of Application Programming Interfaces (APIs) are currently supported:

- Authentication APIs - user authentication on the DMP
- Device APIs - device data transfer as a complete file
- Clinical APIs – transfer of clinical data in separate data clips

Further development of the DMP will focus on enhancing its capabilities and features, providing additional support for advanced data analysis methodologies, visualisation features, and standardisation pipelines.

Data standards

Chengliang Dai | Imperial College London

One of the main goals of the IDEA-FAST project is to identify novel digital measures for fatigue and sleep disturbances. To achieve this goal, a large amount of data, including clinical data (e.g., demographic data of the recruited patients) and device data (e.g., data collected by sensors and wearable devices for monitoring fatigue, sleep and selected activities of daily living), is needed for analysis. Given the scale of the data involved in IDEA-FAST, adoption of data standards brings a few obvious benefits.

First of all, data standards create efficiency by introducing consistent naming of individuals, events, etc., in the IDEA-FAST dataset. Therefore, a standardised dataset enables better data exchange among systems used by different WPs and allows easier reuse of the data to maximise the impact and exploitation.

Secondly, standardising the dataset underpins higher data quality. Errors and mistakes are more likely to be identified during the data acquisition and entry, which helps to reduce the time for cleaning/transforming the data before analysis.

Last but not least, adopting industry recognised data standards raises awareness among industrial partners interested in developing solutions to the problems encountered in IDEA-FAST project.

CDISC Standards for IDEA-FAST

Data standards are normally developed by either government agencies or a group of people and organisations. In IDEA-FAST, we adopted CDISC standards, which are a set of well-defined standards popular in both industry and academia for standardising clinical research data.

CDISC stands for Clinical Data Interchange Standards Consortium. CDISC is an open, multidisciplinary, non-profit standards organization formed in 1997. CDISC standards are supported by over 150 member companies including pharmaceutical companies, biotech companies, contract research organisations or service providers, and technology providers. Moreover, CDISC standards have been adopted by FDA as the mandatory standards for data submissions since 2016.

CDISC has developed different models and standards for different stages in a research process and WP5 has been mainly focusing on developing the standard for the stage of organising the research data in IDEA-FAST.

The CDISC standard for data organisation is called Study Data Tabulation Model (SDTM), which provides a standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting.

As the team that is responsible for developing data management strategy, data standards and the Data Management Platform (DMP), WP5 is working on developing SDTM-based standards for all the IDEA-FAST datasets stored on the DMP.

Other CDISC standards and models include Protocol Representation Model (PRM), that defines a standard for planning and designing a research protocol, Clinical Data Acquisition Standards Harmonization (CDASH), that is the standard which is used for the data collection stage, and Analysis Data Model (ADaM), that defines the dataset and metadata standards that support efficient generation, replication, and review of clinical trial statistical analyses, as well as traceability among analysis results, analysis data, and data represented in the SDTM.

Another important document included in CDISC standards is Define.xml, which describes the metadata for all submitted data structures (SDTM & ADaM).

In IDEA-FAST, data come from quite diversified sources, therefore data standards play an important role in improving the data quality and reducing the time cost for data cleaning/transformation. A standardised dataset also facilitates the data exchange across different studies, potentially increasing the impact of the IDEA-FAST project.

Domains in IDEA-FAST Dataset

In SDTM, data and observations are grouped into a series of standardized domains. Each domain is a collection of logically related observations and contains standard structures, variable names, variable attributes and controlled terminology. Most of the data collected in IDEA-FAST belong to the following domains:

- Demographics (DM)
 - Age, gender, etc.
- Medical History (MH)
- Vital Sign (VS)
 - Blood pressure, height, weight, etc
- Questionnaires (QS)
 - EQ-5D, MFI, etc.
- Functional Test (FT)
 - Actigraphy data, etc.

WP5 will continue developing and maintaining data standards for the IDEA-FAST data stored on the DMP.

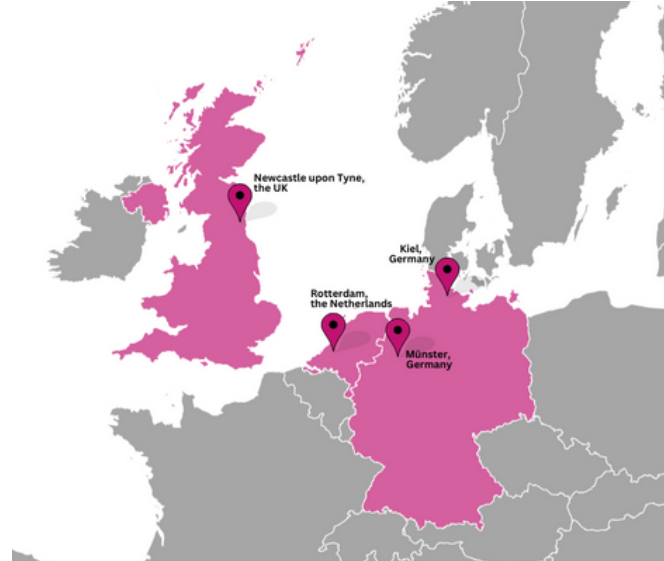
The IDEA-FAST Feasibility Study

Kirsten Emmert | University Hospital Schleswig-Holstein

THE AIM of the feasibility study was to gather information on a variety of potential digital measures captured with different devices and their ability to reflect sleep disturbances or fatigue. Apart from comparing data between different measures from patients with neurodegenerative disorders or immune-mediated inflammatory diseases as well as healthy participants, we also wanted to know, which devices participants find easy or enjoyable to use and are as unobtrusive as possible. This was essential for the larger clinical study that started in 2022, using the most promising subset of tested digital measures which participants are able and willing to use on a daily basis.

The Feasibility Study was conducted across four European sites, where 146 participants (42 healthy volunteers and 104 patients) were recruited at:

- Universität Klinikum Schleswig-Holstein (UKSH), Kiel, Germany
- George Huntington Institut GmbH (GHI), Münster, Germany
- Erasmus Universitair Medisch Centrum (EMC), Rotterdam, Netherlands
- Newcastle Upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK



Considering the timeline of the project, COVID-19 became a hindrance to the preparation of this project.

However, all 4 sites managed recruiting amid the pandemic, with the Kiel site being the first to commence. One of the clinical leads who co-ordinated the patient recruitment process, described the process as challenging but fruitful:

“For me, it was really interesting to get to know the different devices and the digital measures that can be derived from them. Getting continuous health measures from people in their normal surrounding, will help to give us new insights on their diseases and the impact of fatigue and sleep disturbances on their everyday life.”

IDEA-FAST Clinical Lead

She recounts that there were logistical and technological problems in the beginning, but with support from the IDEA-FAST team it was easy to navigate and overcome them. Also, all the participants were entirely dedicated to the project, which made the work much more enjoyable.

“Before giving the devices to our participants, we tried them out in our clinical team. This was a very important step not only to be able to relate to our participants later but also to improve the device setup and support process in collaboration with our colleagues from Newcastle”

“The vast majority of our participants are very interested to see what these devices can do and take great care in making sure they are using the devices correctly. Because we are asking our participants to try out many different devices over the course of four weeks, I was a little worried that their motivation might drop at some point. However, we get the feedback that participants are happy to be involved in this research project and enjoy the weekly interactions with our study team. Moreover, our participants are interested in understanding the collected (sleep and fatigue) data themselves.”

IDEA-FAST Clinical Lead

The participants were happy too: they later reported it was easy to communicate with the research team, and they always felt supported during the project.

“I really liked interacting with my contact person and getting to know the technology throughout the four weeks. I found it very convenient that I only had to come to the hospital once.

I am always interested in exploring new technology and am excited that I could contribute to this international study. Looking at the reports I saw from different devices was very interesting especially for the sleep measures. I feel like there were some devices that captured my waking phases during sleep better than others. In general, I can say that the deep sleep phases reported by the devices match with the previous knowledge of my sleep pattern.”

IDEA-FAST participant



Initial Insights from the Feasibility Study

Kirsten Emmert and Johanna Graeber | University Hospital Schleswig-Holstein

In order to select the most promising digital devices for the Clinical Observation Study (COS), the patient perspective in combination with device data quality and results were taken into account. Besides some quantitative research using questionnaires, two focus groups and 61 semi-structured interviews were conducted (i.e. views of nearly half of all participants were recorded).

The interviews explored ways to reduce the effort of device use, facilitate device use and manage expectations around the study. In general, single small wearable devices and stationary devices were tolerated well, while many participants were bothered by having to use multiple sensors, especially when these included visible electrodes. The use of the multimodal sensor kit was facilitated when sufficient support was provided:

“If I had any queries I could contact the support team for some assistance. So being talked through the process and being shown what to do made it a lot easier”

IDEA-FAST participant

Regarding the use of a headband with EEG electrodes during the night, some found it unobtrusive and easy to use, while others reported considerable interference with sleep:



“But I couldn’t sleep properly because I knew it was there and I thought if I turn over it might come off. And then I was looking at the red light all the time. Because I could see it when I looked up“.

IDEA-FAST participant

Some of the devices needed to be paired with an app, which caused problems in some cases. Therefore, for routine clinical use a device without a patient-facing app might be preferable.

Overall, participants reported that they were happy to participate in the study in order to help future patients with fatigue or sleep problems. One participant said:

“I have the feeling, because of my disability, that I am a bit less useful to society [...]. This was a kind of replacement of work for me, so I really liked that”.

The focus groups explored ways to increase the motivation for study participation even further. A manageable study design, good communication, feedback from the device use periods and information via newsletter were the main points that came up.

The option to have a break in between device use periods and to ensure proper functioning of all devices were named among the most important requirements for the study design. Setting realistic expectations for the study and frequent support opportunities for patients were among the key aspects regarding communication.

In terms of feedback, focus group participants reported that feedback should be easy to interpret and provided regularly. A newsletter including prior participant experiences and progress of the study was mentioned as another potential motivating factor.

In conclusion, the qualitative research from the FS brought up many critical aspects and helped the team to optimize the design of the COS.

Additional points that emerged during this research were included in the COS design as far as possible. For example, a newsletter is now part of the patient communication and a small feedback sheet will be provided to participants at the end of their participation. We hope to draw additional information from the COS, where selected participants will also be interviewed. Here, we will especially focus on experiences and problems during their participation to improve the study procedures and hope to gain more insights into participant motivation and retention.

In addition, we plan to use cognitive interviewing to explore the meaningfulness of fatigue as a symptom to patients and investigate the content validity of the fatigue measurements in the COS.



The IDEA-FAST Clinical Observation Study

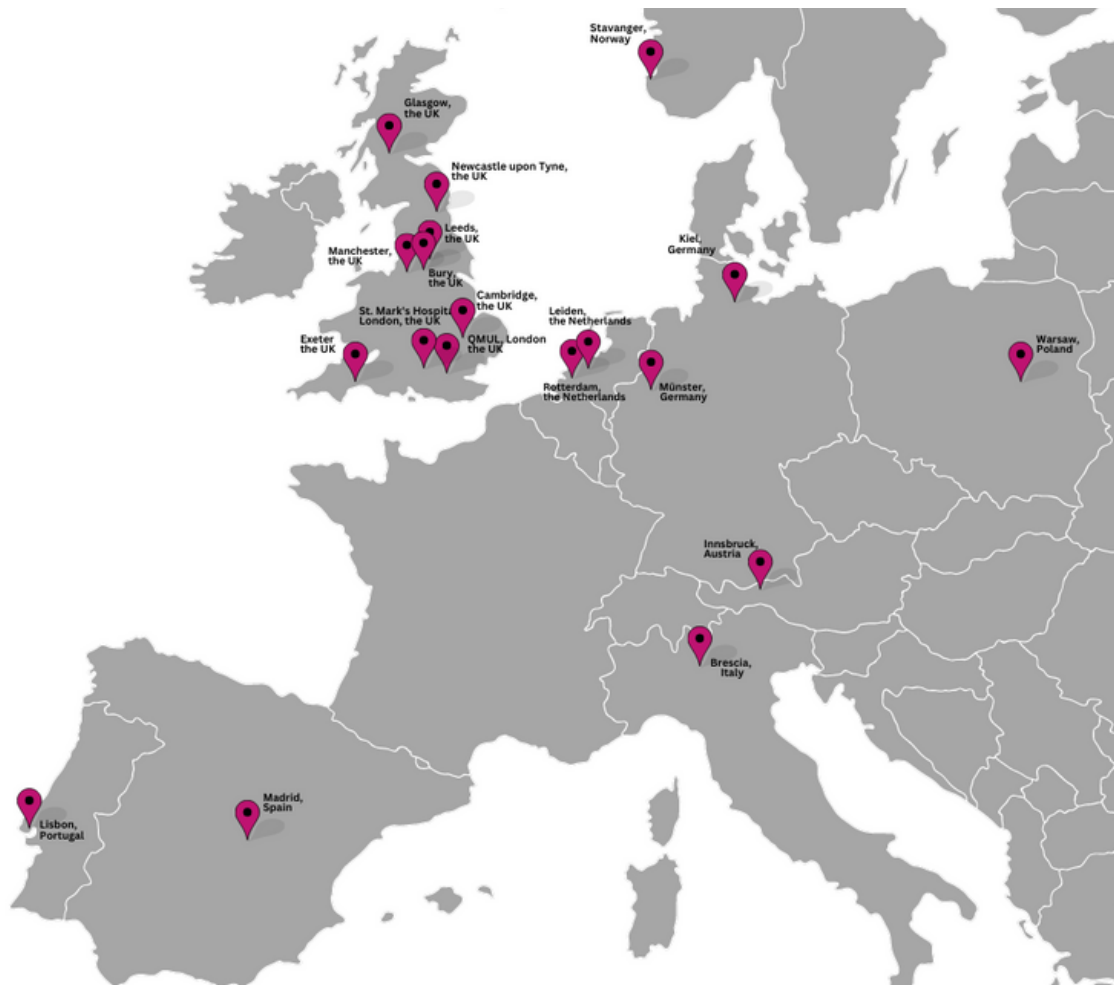
THE IDEA-FAST Clinical Observation Study (COS) is at the forefront of the project's goals. The study aims to analyse the connection between digital and clinical parameters of fatigue and sleep disturbances in neurodegenerative and immune-mediated inflammatory diseases. The COS provides digital tools to record and measure these symptoms directly and thereby more objectively.

In the COS, **2000 participants across 21 sites in Europe are being recruited** – 500 each with Parkinson's Disease and Inflammatory Bowel Disease, 200 each with Huntington's disease, Rheumatoid Arthritis, Systemic Lupus Erythematosus, Primary Sjögren's Syndrome, and 200 healthy participants.

Participants will be monitored during several testing periods over 6 months using selected digital devices and connected mobile apps. Some mobile apps will monitor and collect the device data passively while others will actively interact with participants, and participants receive training and support on how to use them.

Participants are also able to donate biosamples and are invited to keep a daily diary and answer questionnaires, thus reporting on their sleep problems and fatigue levels through multimodal measurements.





21 COS sites among 9 European countries are currently recruiting participants. 2000 participants are expected to be recruited across 6 cohort diseases and healthy volunteers

All the participants receive an informed consent form with a detailed overview of the entire study, and are provided with regular support via email, telephone, and written materials. Two face-to-face consultations and two remote consultations per participant are conducted during the study. Participants wear the selected digital devices for a week after each consultation, followed by self-reports on sleep, fatigue, tiredness, and other parameters.

Results and outcomes from the IDEA-FAST Clinical Observation Study will serve as a vital next step in meeting the challenge of developing composite digital endpoints for fatigue and sleep disturbances.



<https://idea-fast.eu/meet-the-sites/>

Upcoming Analysis

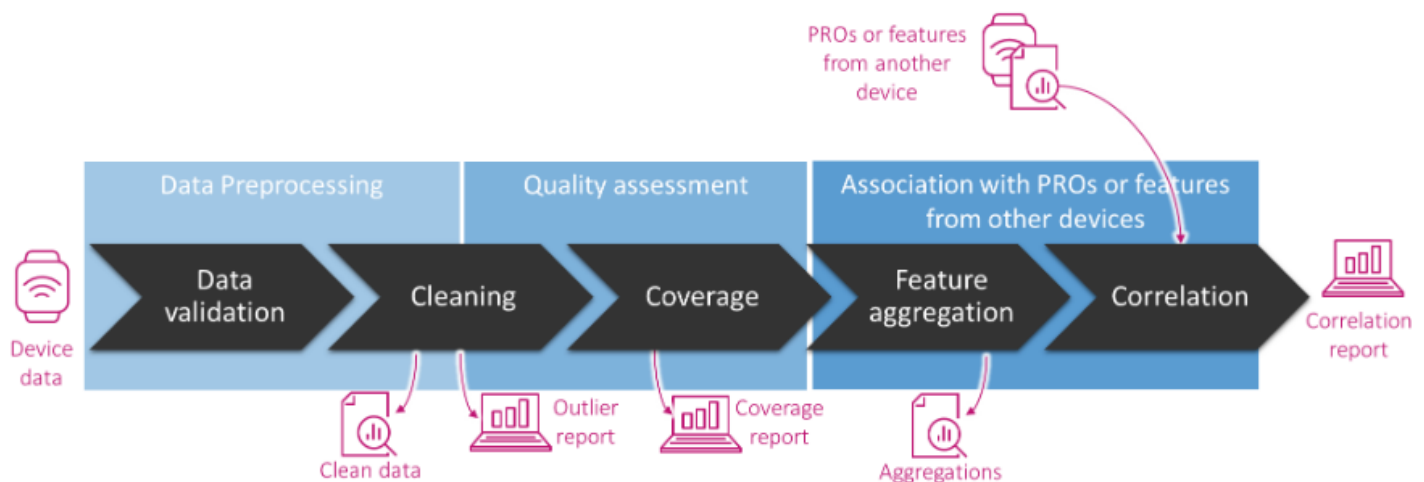
Stefan Avey, WP7 Co-Lead | Janssen R&D

The Clinical Observational Study (COS) is now well underway and work package 7 (Statistical Inference, Design, and Learning) has recently shifted focus from contributing to the design of the COS to planning the analysis of the COS data. A Statistical Analysis Plan (SAP) was drafted over the past 1 year by multiple authors with contributions across work packages. The SAP describes in detail the primary, secondary, and exploratory analyses of the COS.

In brief, the analysis is split into two main sections:

1. identifying a digital biomarker of fatigue (primary) as well as daytime sleepiness or sleep quality (secondary)
2. evaluating the digital biomarkers by characterizing their behavior in each cohort, reliability, validity, and responsiveness.

Writing the SAP has been extremely beneficial to drive greater alignment on the primary goals of the IDEA-FAST project between statisticians / data scientists and clinicians / patients. The plans in the SAP will be put into action starting in 2023 as the team works to begin engineering digital measures from the sensor data and works to identify digital biomarkers.



Schematic representation of the analytics pipeline structure, consisting of three analytical blocks.. The most important intermediate outputs (clean data and aggregations) are presented with file icons in the lower part of the figure, and the output reports are presented with laptop icons. Image taken from Deliverable 4.4

Advisory Boards

IDEA-FAST benefits from the expertise of **THREE ADVISORY BOARDS**, each specialized in essential domains, providing valuable external guidance to the project.

Patient Specialist Advisory Board

Patients are at the forefront and centre of our work. The ultimate goal of this project is to develop measures for fatigue and sleep that are meaningful and relevant to patients' lives. Patient involvement and engagement is thus embedded in all aspects of our work.



Cate Titterton
Crohn's Disease



Dina de Sousa
Huntington's Disease



Heather Hunter
Primary Sjögren's Syndrome



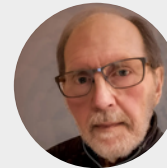
Jen Heather
Rheumatoid Arthritis



Jill
Sjögren's Syndrome



Ulli Funken
Parkinsons



Werner Remmele
Parkinsons

Scientific Advisory Board

The role of the Scientific Advisory Board is to enable effective review of the strategic approach and work performed by the Consortium, as well as to challenge and improve the project to maximize its impact and enable it to meet its objectives.



Aiden Doherty



Ieuan Clay



Sara Riggare

Ethics and Legal Advisory Board

The role of the Ethics and Legal Advisory Board is to provide independent advice from experts in the field. The Board will provide advice on the application of ethical rules, laws and regulations and provide feedback to the Steering Committee.



Klaus Hoeyer



Lynn Rochester



Melanie Goisauf

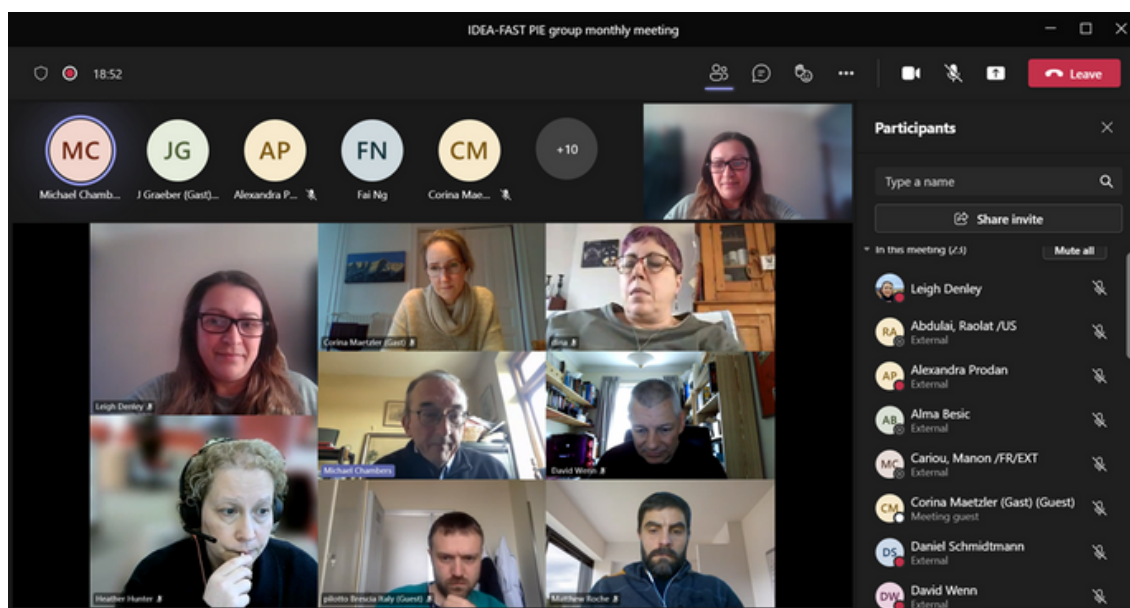
Patient Engagement and Involvement

Patient Involvement and Engagement is a vital part of the IDEA-FAST project, aimed at ensuring that patients remain at the forefront of all research efforts. By actively engaging patients in research, the project leverages their unique perspectives and experiences to drive impactful outcomes.

The IDEA-FAST Patient Involvement and Engagement (PIE) Group comprises a diverse range of stakeholders, including patients, members of patient organizations, researchers, and consortium partners. The group aims to foster open discussions on Patient and Public Involvement and Engagement strategies and issues among consortium partners and external organizations, such as Lupus UK and the European Huntington's Association.

The PIE Group plays a vital role in all project activities, meeting monthly to provide updates on the study and discuss topics requiring public input or plan and discuss further activities. Patients have been involved in several project activities, such as providing feedback on the feasibility study, sharing opinions on the use of digital devices, and contributing to the study design.

The Patient Specialist Advisory Board also plays a crucial role in the governance structure of the IDEA-FAST consortium, providing strategic advice at multiple levels. As a formal advisory body, it helps ensure that patients' voices and perspectives are heard and incorporated into all project activities.



Online IDEA-FAST PIE Group Monthly Meeting during the COVID Lockdown

Collaboration with



Mobilise-D is an IMI sister initiative of IDEA-FAST aimed at improving mobility assessment in patients with chronic obstructive pulmonary disease, Parkinson's disease, multiple sclerosis, and proximal femoral fracture.

Impaired mobility is a major healthcare challenge of the 21st century, and detecting and measuring mobility loss more accurately is crucial. Digital technology, including wearable sensors, has the potential to revolutionize mobility assessment and improve patient outcomes. Many people with chronic conditions or injuries experience reduced mobility, which can significantly impact their quality of life. By implementing mobility assessment as a standard clinical practice, healthcare professionals can detect changes earlier and tailor treatments to individual patients more effectively. Digital mobility assessment can also help address a major public health problem, as mobility loss due to aging and chronic disease is becoming increasingly prevalent. Moreover, the use of digital technology to assess mobility has the potential to lead to more successful clinical trials and ultimately improve patient care.

Mobilise-D and IDEA-FAST have joined forces to advance their efforts in using digital endpoints to improve the lives of chronically ill patients. The topics of collaboration include areas such as ethics, principles of external data-sharing, regulatory approaches, dissemination activities, training and education, and stakeholder engagement.

One of the collaborative efforts between Mobilise-D and IDEA-FAST is the DIGITAL HEALTH CATALYST, programme that aims to foster the next generation of digital health researchers and professionals. The Digital Health Catalyst provides early career researchers from academia and industry exposure to a rich scientific environment, training, publishing assistance, networking, and more.



Find out more:

<https://digitalhealthcatalyst.org>



Find out more: <https://mobilise-d.eu>



Collaboration with Neuronet

NEURONET is a Communication and Support Action that aimed to connect research initiatives on Neurodegenerative diseases, help scientists identify gaps in research, and make their findings more accessible for the general public. The Neuronet platform included 24 projects with an overall funding of €386 Million, representing 270 organisations across 25 countries.

The project produced valuable assets, including the Neuronet Knowledge Base. The Knowledge Base provides a summary overview of the IMI neurodegeneration research portfolio through its interactive dashboard and includes links to over 500 publications and more than 380 publishable deliverable reports, acting as a one-stop shop to explore the diverse projects and outputs of the portfolio. Furthermore, the Knowledge Base offers access to a regulatory, health technology assessment & engagement Decision Tool to help researchers identify the key processes and procedures for engagement with these stakeholders at key points in the development of an asset.

Neuronet has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 821513 from March 2019 until August 2022.

IDEA-FAST was represented in Neuronet in multiple occasions:

- Presentation during a Neuronet session at the 2022 Alzheimer Europe Conference about Patient Involvement and Engagement in IDEA-FAST
- Coverage of project updates on the NEURONET website, newsletters, Twitter & other social media channels
- Neuronet Brain Awareness Month 2021
- Participation in various meetings, including the Neuronet Working Group meeting on data sharing, participation in Scientific Coordination Board meeting, Communication expert community meeting
- Project overview in Knowledge Base & website.
- Participation in various workshops, including the jointly organised workshop on digital endpoints during ISPOR Europe 2021 & participation in joint outreach activity.

Read more on

<https://imi-neuronet.org>

Early Career Researchers Spotlight

IDEA-FAST is delighted to introduce the „Early Career Researcher Spotlight“ - IDEA-FAST's newest initiative - presenting our team of young scientists, the Doctoral and Postdoctoral fellows who are making substantial contributions towards achieving IDEA-FAST's goals. Throughout this series of interviews, we aim to learn more about the specialisation and professional interests of the researchers, as well as their current efforts in the project.

Dr. Chloe Hinchliffe is a postdoctoral researcher in the Brain and Movement (BAM) Research Group at Newcastle University. She is working with data from a MoveMonitor device placed on the lower back of participants, from which she analyses their gait characteristics. [Read more here.](#)



Dr. Jennifer Kudelka is a medical doctor and researcher at the Department of Neurology of the University Hospital in Kiel. She is involved in the organizational aspects, like working on the implementation of the Clinical Observational Study, and scientific analysis of the IDEA-FAST project. [Read more here.](#)



In the coming weeks we will be introducing other researchers from our teams.

Engagement with regulatory authorities

The ultimate goal of the IDEA-FAST project is to identify digital endpoints for measuring fatigue and sleep disturbances to support development of new treatments. Therefore, it is important that we engage with appropriate regulatory authorities effectively.

In this regard, at the start of the project, we met with the Innovative Task Force (ITF) of the European Medicines Agency (EMA) to discuss the concepts and approaches of the IDEA-FAST project. We were pleased to receive general support from the ITF the concepts and importance of the development of digital endpoints for fatigue and sleep problems. ITF also suggested us to seek advice from the Scientific Advice Working Party (SAWP) when we have completed the IDEA-FAST feasibility study.

In 2022, we met with the EMA SAWP to discuss our Feasibility Study data and the design of the Clinical Observational Study. We were delighted to receive general support of our aim to develop a cross-disease digital endpoints for fatigue and sleep problems, as well as the overall approach to identify these digital endpoints.

We also actively engaged with the Health Technology Assessment (HTA) regulatory authorities. For example, we took part in a HTA and regulatory interactions Working Group in February 2021 on HTA engagement in the development of digital endpoints, covering topics such as the experience and expectation of HTA bodies with regard to the use of digital endpoints, the environment in which digital endpoints data will be collected and the optimal approaches to engage with HTA bodies.

David Nobbs, Digital Biomarker Technology and Science Lead at Roche and WP9 Co-lead, represented IDEA-FAST in a panel discussion on digital endpoint at the virtual ISPOR Europe Conference in December 2021.

In addition, we participated in several multi-stakeholder digital health technology and digital endpoint workshops in 2022 which include academia, industry and regulatory authorities such as the EMA and the US Food and Drug Administration (FDA).

IDEA-FAST 2023 General Assembly

We are thrilled to announce that the IDEA-FAST 2023 General Assembly, our first in-person meeting after the pandemic, was a great success! The event was held in Barcelona on 16 and 17 March, with attendance of 100 consortium members from 40 organizations, both in person and online, including attendees from the clinical sites. The meeting included plenary and breakout sessions that enabled us to review the project's progress and future requirements, identify new growth opportunities, and strengthen communication among consortium members.



The assembly also featured a poster session with 17 participants, during which consortium members presented their posters, and attendees voted on their favourite. We are delighted to congratulate the winners of our poster sessions:

- Johanna Graeber with a poster titled “Technology Acceptance of digital devices. A qualitative sub study of the IDEA-FAST Feasibility Study” secured the first place.
- Clémence Pinaud with a poster titled “Overview of the Statistical Analysis Plan of the IDEA-FAST Clinical Observational Study” was awarded the second place.
- Adrien Bennetot with a poster titled “Investigating patient-reported fatigue in immune-mediated inflammatory disorders and neurodegenerative diseases” came in third place.

The poster session was a highlight of the assembly, and we congratulate all of the winners and participants for their outstanding contributions.

In addition to the Work Package Meetings and progress updates, we included sessions of COS study site meetings, to discuss the challenges that have come up so far during patient recruitment and to identify mitigation strategies and solutions to any current or foreseen impediments.

Despite the challenges posed by COVID-19, we are proud to report that IDEA-FAST has continued to make significant progress in advancing the Clinical Observational Study (COS) recruitment process, digital technology, and data analysis.

We remain committed to accelerating our activities over the next few months, including participant recruitment, improving COS data quality, and maintaining our patient and public engagement.

We are excited about the progress we have made so far, and we look forward to continuing our efforts to advance towards achieving the goals of the IDEA-FAST project.



The IDEA-FAST Consortium during the General Assembly in Barcelona, March 16-17, 2023.

What is next

The IDEA-FAST project is entering its second half now: many milestones have been achieved, and there are still many more to come, and things to look forward to. The COS study has successfully been launched and is currently ongoing. Looking ahead, our key tasks are to accelerate our recruitment to the COS and to ensure collection of high quality clinical and digital data, to prepare for our biomarker identification using COS data, to further develop our dissemination, engagement and sustainability strategy and to continue our work on ethical, legal and data privacy regarding the use of digital assessments in the natural environment.

From BITS to BETTER Workshop

IDEA-FAST, Mobilise-D and Radar-AD are prominent large IMI (now IHI) projects working on digital endpoints or digital biomarkers, which keep a patient-centric approach. In collaboration, these projects are organizing a face-to-face workshop, which will bring together patient representatives, researchers, ethical and legal scholars, physicians, and those involved in patient involvement and engagement in several IMI projects as well as others involved and interested in the development of digital endpoints.

This workshop will be held in Berlin, from June 22nd to June 23rd, led by Lygature.

ISPGR World Congress 2023

The International Society of Posture & Gait Research (ISPGR) World Congress brings together posture and gait researchers and clinicians from around the world for discussion and exchange of the most cutting edge knowledge. Chloe Hinchliffe, postdoctoral researcher in the Brain and Movement (BAM) Research Group at Newcastle University will make an oral presentation on “Are measures of gait variability associated with sleepiness and fatigue in immune and neurodegenerative disorders? Insights from the IDEA-FAST feasibility study.”

This congress will take place in Brisbane, Australia, from July 9th to July 13th. You can read more on the IDEA-FAST website.

Stay updated: <https://idea-fast.eu/events/>



Upcoming IDEA-FAST Webinar

The next upcoming webinar in IDEA-FAST will take place on June 7th 2023 from 2:00 to 4:00 PM CET. Our distinguished panel of speakers will share their expertise on chronic illnesses, and the challenges of fatigue and sleep disturbances faced by patients. We will also discuss the current digital approaches that are being researched in IDEA-FAST to assess these ailments, and how they could aid in the improvement of current research and treatment opportunities. The webinar will offer ample opportunities for participants to engage in discussions with our panelists, and ask questions

Whether you are a healthcare professional, researcher, patient, or simply interested in learning more about the IDEA-FAST patient cohort diseases, this webinar promises to be an informative and engaging event, with something for everyone interested in the topics of fatigue, sleep disturbances, digital assessment, and chronic diseases.

We invite you to join us for this exciting event. Registration is now open and free for everyone, and we encourage you to sign up early to secure your spot.

New Ways of Measuring Fatigue and Sleep Disturbances in Chronic Diseases

June 7th 2023
14:00 to 16:00 Central European Time



Register here



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