IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

WP6 – Clinical Validation Study Organisation and Management

D6.2: Finalised master documents in English for ethical/regulatory submissions, including study protocol & PIS/ICF for the COS

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Due date	31 OCT 2021
Delivery date	09 MAY 2022
Deliverable type	R
Dissemination level	PU

Document History

Version	Date	Description
V0.1	25 APR 2022	First version
V0.2	28 APR 2022	Version for internal review
V1.0	09 MAY 2022	Final version

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1 Abstract

Deliverable D6.2 provides the study protocol V2.0 & participant information material for the clinical observational study (COS). As the study will be observational in nature and the focus is on identifying and evaluating digital parameters of fatigue, sleepiness and sleep disturbances in general, the consortium decided to rename the study "COS" to avoid the impression that the focus is on validating specific digital devices. The COS will follow 2,000 participants (500 subjects each for PD and IBD, 200 each for HD, RA, SLE, PSS and healthy controls). The study will run for 29 months, and each participant will be enrolled for a period of 24 weeks. During this time, each participant will attend two study visits at the recruitment centre (at week 0 and week 24 of their respective study period) as well as two remote visits in between (at week 8 and 16). During the visits, participants undergo a comprehensive assessment of demographic and clinical aspects as well as a granular assessment of fatigue, sleepiness and sleep disturbances using current reference tools (e.g. patient-reported outcomes, PROs). Furthermore, data on mood and pain are collected. Following each face-to-face / remote visit, participants use a combination of digital health technologies in their own environment for one week each. This is designated the technology use period (TUP). We selected two digital health technologies (and an additional one on an optional basis) based on the results of the Feasibility Study (FS), feature engineering exercises, analyses of relevant extant datasets and a literature review. Concomitant data on fatigue, sleep, selected ADLs and other confounding variables, together with other relevant contextual information will be collected remotely up to three times a day during the period of digital health technology use with Apps. The inclusion of two remote visits will enable us to collect data on acceptability, feasibility and operational challenges of the future use of these digital endpoints in a remote decentralised setting, and permits direct comparison of data quality and patient compliance in a remote study versus a clinical study. As far as possible in the framework of an observational study, blood, urine and stool samples will be collected for biobanking. Our cohorts will be drawn from 17 centres across 10 countries within Europe, representing geographic, ethnic and healthcare diversity.

2 Introduction and actual status of the documents

This deliverable was postponed in order to take into account any important points raised by EMA during our regulatory interactions and also in the Qualification Advice that we have recently received.

Development of the COS Protocol started in early 2021 and was further refined following review by the Clinical Knowledge and Insight taskforce and a device selection meeting in July 2021. The content and structure of the document was substantially influenced by the above-mentioned interaction with the EMA, and the feedback we received from the IDEA-FAST EMA working group. Moreover, all work packages were invited to comment on the protocol and the participant information and consent material, especially patient representatives, statisticians, engineers and stakeholders from pharma with substantial knowledge with regard to recruitment strategies and giving feedback to participants. The final version was submitted on 25th April 2022 as an adapted version in Kiel and Münster, after having feedback on the first submitted version from the ethical boards of Kiel, Münster, Brescia, Ireland, Norway (all have approved the study), Innsbruck, Madrid, and United Kingdom. Accordingly, the final version will be submitted to the respective ethics committees in participating countries.

Appendix A and Appendix B contain the final Informed Consent Form (ICF) and Patient Information Sheet (PIS), respectively, as submitted in Kiel on 25th April 2022. Appendix C contains the final COS protocol as submitted in Kiel on 25th April 2022. Note, however, that the PIS and COS protocol are confidential documents. Therefore, there are two versions of this current deliverable report – a confidential version which includes the full PIS and COS protocol, and a public version with the PIS and COS protocol removed.

3 Conclusions

In conclusion, the COS will offer a unique opportunity to identify and evaluate composite digital parameters of fatigue, sleepiness and sleep disturbances. The COS protocol and PIS/ICF have been finalised and include feedback from all key stakeholders across the IDEA-FAST consortium including patients, clinicians, statisticians and engineers. The ethical submission processes at all participating clinical sites are running smoothly and we expect all involved sites to have a positive ethics approval by the official start of the COS on 1st June 2022.

Appendix A – *Final ICF (version 2) as submitted in Kiel on 25 April 2022*

Title of Project: Clinical observational study on the relationship between digital and clinical parameters of fatigue and sleep in neurodegenerative disorders and immune-mediated inflammatory diseases

(Lay title: Finding the best methods to measure sleep and fatigue in daily lives using digital technology)

Please initial the boxes against the statements that apply to you

1. I confirm that I have read and understand the Participant Information Sheet dated 24 September 2021 (version 1.0) for the above study and have had the opportunity to consider the information and ask questions. ☐

2. I understand that my participation is optional and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I give permission to the IDEA-FAST consortium for keeping my data for up to 25 years and for my data to be used for future research related to fatigue, sleep, immune-mediated inflammatory diseases or neurodegenerative diseases, and without my additional consent provided it has been approved by the steering committee of the IDEA-FAST consortium or their delegated sub-committee. ☐

4. I am willing to be contacted for future research studies or clinical trials related to fatigue, sleep, immune-mediated inflammatory diseases or neurodegenerative diseases. ☐

5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by researchers of this study, and individuals from the relevant regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

6. I agree to my General Practioners (GP) being informed of my participation in the study. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Participant taking consent	Date	Signature

Optional consent to Biosample donation:

8. I agree to donate the following biological samples to Newcastle University, who acts as custodian of my samples on behalf of the IDEA-FAST consortium

   I give permission to the IDEA-FAST consortium for keeping my biological samples for up to 25 years and for my samples to be used for future research related to fatigue, sleep, immune-mediated inflammatory diseases or neurodegenerative diseases, and without my additional consent provided it has been approved by the steering committee of the IDEA-FAST consortium or its delegated sub-committee.

   I understand that my samples are a gift to the Newcastle University, United Kingdom, and I do not expect a financial benefit as a consequence of my donation.

Urine samples	☐ Yes	☐ No
Stool samples	☐ Yes	☐ No
Blood samples (Blood draw as part of a clinical examination, with collection of 22 ml for study-related analyses)	☐ Yes	☐ No
Blood samples (22 ml taken as study-related blood draw)	☐ Yes	☐ No

Optional consent to participate in a qualitative interview

9. I agree to participate in a qualitative interview for providing information about individual experiences and problems during IDEA-FAST participation.	☐ Yes	☐ No

Optional consent to participate in a web-based cognitive test battery (once during all Technology Use Periods, 25 min in total)

10. I agree to participate in a 25 min web-based cognitive test for validation of the cognitive tests performed on the CANTAB app.	☐ Yes	☐ No

Optional consent to wear the Dreem3 device

11. I agree to wear the Dreem3 device during one of the 4 Technology Use Periods for 2 nights.	☐ Yes	☐ No

Appendix B – *Final PIS (version 2) as submitted in Kiel on 25 April 2022*

For confidentiality reasons, the Patient Information Sheet is not included in the public version of this deliverable.

Appendix C – *Final COS protocol (version 2) as submitted in Kiel on 25 April 2022*

For confidentiality reasons, the Clinical Observation Study protocol is not included in the public version of this deliverable.