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

D6.4: First study subject approvals package of the COS

Lead contributor	P2 – UKSH
Other contributors	P1 – UNEW, P7 – ECRIN, P43 – SARD

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Document History

Version	Date	Description
V0.1	25 APR 2022	First version
V0.2	12 MAY 2022	Minor revisions after internal review
V1.0	23 MAY 2022	Final version

Table of Contents

1 Abstract

Deliverable D6.4 provides the first study subject approvals package of the Clinical Observation Study (COS; formerly clinical validation study – CVS). This includes the registration number of the COS, a short report on the ethical approval status at all sites, and the document of the ethics board of the Sponsor (ethical committee of the Medical Faculty, University Hospital Schleswig-Holstein, Kiel, Germany) that reports about approval of the COS for Kiel site.

2 Introduction and status of documents

This deliverable is slightly delayed due to the EMA interaction process, and to enable the IDEA-FAST consortium to implement the outcome of this interaction process, i.e. the EMA qualification advice, into the final version of the COS protocol and participant information material (see further details, including information about COS protocol development in D6.2).

Submissions of the IDEA-FAST COS protocol to local ethics boards started in October 2021.

3 Registration number of COS

The study is registered in the German Clinical Trial Registry (DRKS, https://www.drks.de/) under the number DRKS00027946. The direct link to the study is as follows: https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00027946.

4 Ethics approval of the COS by the Ethics Committee Kiel

Ethical approval has been obtained at seven sites so far (green rows in Table 1). The second version of the study protocol has been fully approved by the Ethics Committee of the Medical Faculty, Kiel University (26 April 2022). Please note that the first version of the study protocol, which comprehensively depicts the structure of the study, is still in circulation with some ethics committees, and that after receipt of the favourable opinion for this first version, the second version (V02, as an amendment or as an adapted version) has been or will be submitted later.

Table 1: Ethics submission status in participating countries (updated 12 May 2022).

Country	EC Submission	EC Approval
GER (Kiel)	20Oct2021: Submission of COS protocol V1.0 24Apr2022: Submission of COS protocol V2.0	03Nov2021: Favorable Opinion for COS V1.0 26Apr2022: Favorable Opinion for COS V2.0
GER (Muenster)	21Jan2022: Submission of COS protocol V1.0	18Feb2022: Favorable Opinion for COS V1.0
IRE	07Feb2022: Submission of COS protocol V1.0	22Feb2022: Favorable Opinion for COS V1.0
ITA	Jan28th: Submission of COS protocol V1.0	31Mar2022: Favorable Opinion for COS V1.0
POL	31Mar2022: Submission of COS protocol V1.0 11May2022: Resubmission with COS protocol V2.0	04May2022: Favorable Opinion for COS V1.0
ESP	30Mar2022: Submission of COS protocol V1.0 29Apr2022: Resubmission with COS protocol V2.0	8Apr2022: EC requesting further information 04May2022: Favorable Opinion for COS V2.0
NOR	11Jan2022: Submission of COS protocol V1.0 08Mar2022: Additional information provided to EC 06May2022: Resubmission with COS protocol V2.0	28April2022: Favorable Opinion for COS V1.0
GBR	18Feb2022: Submission of COS protocol V1.0 29Apr2022: Resubmission with COS protocol V2.0	30Mar2022: Provisional Opinion for COS V1.0
AUT	19Jan2022: Submission of COS protocol V1.0 Pending: Resubmission with COS protocol V2.0	10Feb2022: Provisional Opinion for COS V1.0
PRT	23Mar2022: Submission of COS protocol V1.0	Evaluation of COS V1.0 ongoing
NDL	Submission pending	

5 Conclusions

The IDEA-FAST COS has been listed on the DRKS registry. The COS ethics approval V1.0 has been submitted to the ECs in all participating countries, except for the Netherlands. The 7 different ethics committees have approved the COS V1.0, including the board of the Sponsor site at UKSH in Kiel, Germany. The next step will be to obtain ethics approval for all remaining sites, either with COS V1.0 (in case of PRT, as the evaluation is still ongoing) or with COS V2.0 (in case of the Netherlands, as the submission is pending). The resubmission to the ECs, in GBR, was performed with COS V2.0. In AUT, the resubmission will be performed with COS V2.0 and it is in preparation. In other countries with COS V1.0 approval, an amendment would be submitted to the ECs. Note that the start of the COS recruitment is planned for 1st June 2022, and the COS V1.0 approval is sufficient for this.

Appendix A – Final ethics approval from Kiel site

MEDIZINISCHE FAKULTÄT
DER CHRISTIAN-ALBRECHTS-UNIVERSITÄT ZU KIEL

ETHIK-KOMMISSION

A.D. 1665

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AZ.:	**D 616/21** (bitte stets angeben)
Studienplan:	**Beobachtungsstudie über den Zusammenhang zwischen digitalen und klinischen Parametern von Müdigkeit und Schlaf bei neurodegenerativen Erkrankungen und immunvermittelten Entzündungskrankheiten, im Rahmen des IDEA-FAST Projekts**
In Bezug auf:	**Pilotstudie D 491/20: *Eine Beobachtungsstudie zur Beurteilung von Schlaf und Fatigue mit digitaler Technologie im häuslichen Umfeld im Rahmen des IDEA-FAST Projekts***
Antragstellung und Studienleitung:	**Prof. Dr. Walter Maetzler, UKSH Kiel**
In Kooperation:	**Prof. Dr. Hanna Kaduszkiewicz, Prof. Dr. Stefan Schreiber UKSH Kiel**
Sponsor:	**UKSH Kiel**
Finanzierung:	**Forschungsprojekt *IDEAFAST,* European Union's *Horizon 2020***
Erst-Antrag vom:	**20. Oktober 2021 (Eingang 01. November 2021)**
Amendment vom:	**24. April 2022 (E-Mail)** **Überarbeitung von Patienteninformation und Protokoll** Studienprotokoll sowie Aufklärung und Einwilligung jew. V2.0 24Apr22, IDEA FAST Poster (EN); CLINIC CRF/Fragebogen V1 IBD v2.0 220421 (EN, D); CLINIC CRF/Fragebogen V1 PD v2.0 220421(EN, D); CLINIC CRF/Fragebogen V1 PD v2.0 220421(EN, D)

Sehr geehrter Herr Kollege Maetzler,

wir bestätigen den Eingang und die Kenntnisnahme des Amendments zu oben genannter Studie.
Nach Durchsicht der Unterlagen durch die Geschäftsstelle und durch mich als Vorsitzenden der Ethik-Kommission bestehen gegen das Amendment und die Fortführung der Studie keine berufsethischen und berufsrechtlichen Bedenken. Es wurden keine wesentlichen Änderungen hinsichtlich Studieninhalt und Untersuchungsprotokoll vorgenommen.
Wir weisen darauf hin, dass datenschutzrechtliche Aspekte von Forschungsvorhaben durch die Ethik-Kommission grundsätzlich nur kursorisch geprüft werden. Dieses Votum ersetzt nicht die Konsultation des zuständigen Datenschutzbeauftragten.
Wir wünschen für die Durchführung der Studie viel Erfolg.

Mit freundlichen kollegialen Grüßen

Prof. Dr. med. H. M. Mehdorn
Vorsitzender der Ethik-Kommission

Dr. med. Christine Glinicke
Geschäftsführung der Ethik-Kommission