

D2.3 First study subjects approvals package [confidential]

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Summary

This document details the protocol for the technical validation study in the Mobilise-D project, where specifically the design, recruitment, and data collection will be described. Ethical considerations at the three sites will also be described along with registration of the study protocol prior to inclusion of the first participant.

The Mobilise-D technical validation study is a multisite validation study evaluating physical activity in real life settings. This study aims to verify and test the device-algorithm pair to be used in the further studies of the overall work of the Mobilise-D consortium. The technical validation study has an observational design that measures walking in both controlled, simulated and real-world settings, and evaluates the experiences of both participants and professionals that are using the device. In addition, the study will help us to understand several of the practical issues associated with using this type of technology in clinical research.

The full title of the study is “Validating digital mobility assessment using wearable technology – the Mobilise-D Technical Validation study”, with a short acronym: “Mobilise-D – Technical Validation Study”. The Mobilise-D – Technical Validation Study will be conducted in order to validate the system prior to the clinical validation trial, which is the next step of the Mobilise-D project.

The Newcastle upon Tyne Hospital NHS Foundation Trust (NuTH) will act as the Sponsor for the entire study, including sites based outside the UK. As sponsor, NuTH has the responsibility for ensuring the appropriate regulatory and ethical approvals are in place as required.

The technical validation study will be performed at five sites located in the UK (UNEW and USFD), Israel (TASMC), and Germany (CAU and RBMF). All test sites obtained ethical approvals in September 2019. An amendment to the protocol was submitted for approval in January, and at the time of this deliverable, the UK have received approvals but are waiting for local approval at Sheffield and Newcastle before the recruitment can start. The deliverable

was produced before the pandemic, and the parts of the work that will need to be amended due to COVID-19 will be described to the ethical committees if needed.

The trial has been registered (ISRCTN12246987).

This deliverable reports on the first study subjects' approvals package, including the protocol for the technical validation study, ethics approvals, and study registration. We also include a short description of study progress at the end of this deliverable.

The deliverable starts with an introduction (Section 3). Section 4 continues with the study protocol, presenting the crucial parts of the trial. Section 5 presents the ethical considerations and section 6 reports on study registration. Section 7 contains the status prior to the inclusion of the first participant for the Mobilise-D technical validation study.