D4.3 First study subject approvals package of the CVS [Confidential Deliverable]

Submitted: December 2020

Summary

The deliverable includes the final version of the Mobilise-D clinical validation study (CVS) protocol, the registration number of this CVS, and information about the first ethical approval of the CVS by Sponsor.

Efforts to mitigate loss of mobility in old and vulnerable cohorts are an increasing priority in clinical management, research and policy, and promising interventions are now under investigation. To target mobility loss effectively, wearable digital technology (small devices worn on the body that measure movement) can be used to measure and monitor real-world walking speed (RWS) and other digital mobility outcomes (DMOs). The EU-funded IMI consortium Mobilise-D aims to demonstrate that DMOs can successfully predict relevant clinical outcomes. The first stage of this project was a technical validation of a device-algorithm pair to measure RWS and other DMOs (see e.g. D2.3). The second stage of the project (ie, the study described here) aims to use this technically validated device-algorithm pair to link DMOs to clinical endpoints for regulatory approval.

The Mobilise-D CVS is a longitudinal observational cohort study conducted in ten different countries across 16 different sites. The study aims to enrol 2400 participants from four different disease cohorts (600 each); Chronic Obstructive Pulmonary Disease (COPD), Parkinson's disease (PD), Multiple Sclerosis (MS) and Proximal femoral fracture (PFF).