D5.1 Regulatory Plan [confidential]

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Summary

Any new medicinal product, before it can be sold in the European Union, must receive a marketing authorisation from the European Medicines Agency (EMA), which is provided if the company developing and marketing the medicinal product produces extensive technical, pre-clinical and clinical evidences that the new drug is safe and effective, and of the right quality. These evidences must be produced with clinical, statistical, or instrumental methodologies that the EMA considers adequate. When a new methodology is developed, it is best practice to obtain from EMA a Qualification Opinion that recognises the methodology adequate for a specific context of use. Most of the qualified methodologies are clinical or biochemical; the use of advanced technologies in clinical trials is still relatively new, and their regulatory qualification is still extremely challenging.

This document provides a description of the strategy that the Mobilise-D consortium is adopting to pursue the regulatory qualification of the new methodologies under development in the project. Mobilise-D aims to develop wearable sensors and analytics software capable of providing reliable quantification of digital mobility outcomes over sufficiently long periods (e.g. a week) in real world conditions. Digital Mobility Outcomes quantify mobility performance, intended as the actual level of mobility (both in term of duration and of intensity) that the patient undertakes during their daily life.

To evaluate the efficacy of a new drug in clinical trials, patients' mobility is routinely assessed only in terms of mobility capacity (how capable of mobility is the patient during a standardised test in the hospital) and/or mobility perception (how active the patient subjectively sees himself, as depicted through questionnaires). Mobilise-D believe the quantification of mobility performance is essential to properly measure the degree of mobility disability in each patient, and the efficacy of a new drug to slow down or even reverse the progression of such disability.

The staged approach developed to pursue the EMA qualification advice has already been praised by the regulator itself. The first request for qualification advice, relative to the use of digital mobility outcomes as biomarkers to monitor the progression of Parkinson's disease, received a positive evaluation. Mobilise-D are currently pursuing a second qualification advice, this time to extend the use to multiple sclerosis, outcome of proximal femoral fracture and Chronic Obstructive Pulmonary Disease. The project expects to complete the advice procedure by November 2020, well in time for the start of clinical validation trial, referred herein as observational clinical trial.