D4.1 Updated systematic review on primary and secondary clinical endpoints [confidential]

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Summary

Advances in wearable sensor technology now enable frequent, objective monitoring of real- world walking in clinical research. However, it is not yet clear which digital mobility outcomes (DMOs) are most suitable for use as research instruments. To address this gap, the Mobilise-D research program aims to deliver, validate, and obtain regulatory approval for a suite of real- world DMOs. To this end, we are conducting a series of reviews within WP4 and in collaboration with WP2 and WP6 to understand the validity and value of DMOs from regulatory, clinical, and patient perspectives.

The first review will systematically analyse how many and which types of mobility endpoints are assessed as primary, secondary or exploratory outcomes in regulatory submissions to the European Medicine Agency. In the second review, we will explore the evidence on DMOs' construct validity, prognostic value, and responsiveness to intervention through a scoping review of existing literature. The third review is a qualitative systematic review which aims to identify and synthesize personal perspectives on real-world walking within the context of chronic conditions.

All three reviews are currently in progress. In this deliverable, we report the objectives, research questions, protocol, current status, project plan and, where available, preliminary results of each review. Findings from these reviews will be used to support the selection of DMOs for validation within each of Mobilise-D's disease-area cohorts in WP4, inform the instruments and outcomes measured in each of the WP4 studies, support the regulatory activities of WP5, and verify the analysis plan developed by WP6. Upon completion, findings will also be disseminated to the public through a series of scientific publications and in collaboration with the communication team in WP7.