

D4.4 Midterm recruitment report [confidential]

Submitted: August 2021

Summary

This document details the midterm recruitment status for the clinical validation study in the Mobilise-D project, where specifically the recruitment status, mitigation plans, and methods for monitoring recruitment will be described. Considerations due to the COVID-19 status at the sites and changes due to the pandemic are described as well, along with planned and already initiated mitigation strategies to meet the target recruitment numbers.

In summary, the first participant was recruited on the 5th of April, 2021, that is, according to the pre-specified plan. Status on July 19th 2021 is that 440 of expected 451 participants have been recruited. Overall, we aim to recruit 2,400 participants from four patient cohorts. In order to achieve the targeted recruitment numbers given the varying local pandemic-related circumstances at participating sites, we have amended the protocol in that the recruitment period was extended from 6 to 12 months. With these changes of the original recruitment plan and end date as well as highly detailed mitigation plans in place, we expect to meet our targeted number of participants. This will be updated in October 2021 prior to the review meeting scheduled for Nov 4th 2021.