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An Integrated Solution for Sustainable Care for Multimorbid Elderly Patients with Dementia

CAREPATH

WP5: CAREPATH Clinical Investigation

D5.4: Patients recruitment and follow-up report

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Executive Summary

The objective of this deliverable is to provide a comprehensive overview of the patient recruitment and follow-up process carried out at the clinical sites. Although initially intended to cover all planned clinical sites (Spain, Romania, the United Kingdom, and Germany), the investigation was ultimately implemented only in Spain and Romania due to regulatory and administrative constraints. This report builds upon the information presented in deliverable “5.3. Midterm Recruitment Report” and includes updates regarding the inclusion, retention, and follow-up status of all participants enrolled at the active sites.

In addition to the Clinical Investigation (CI), this deliverable also summarises the recruitment activity related to the Technical Validation and Usability (TVU) phase. A total of 4 participants were included in Spain between September 2024 and January 2025, and another 4 participants were included in Romania between March and June 2025. In the United Kingdom, despite extensive efforts and the screening of 477 potentially eligible patients, no participants could be included due to the restrictive nature of the inclusion and exclusion criteria. In Germany, ethical approval for patient involvement was not granted, and no recruitment activities were initiated.

A total of 8 participants were enrolled in the CI: 6 in Spain and 2 in Romania. In the Spanish site, one participant decided to withdraw from the study during the final month. Nevertheless, with the informed consent of both the participant and their informal caregiver, all planned visits were completed and all required data — including the final visit — were successfully collected. In Romania, one participant withdrew from the study after one month due to health reasons unrelated to the CAREPATH platform. This participant was subsequently replaced, allowing the study to continue with two enrolled patients and their informal caregivers. Both completed the study protocol and follow-up without incident.

The clinical investigation period will continue until July 25th, allowing for the completion of the three-month follow-up for the last participants enrolled, in accordance with the plan outlined in the “5.3. Midterm recruitment report.” No major delays or protocol deviations have occurred, and all activities have been conducted in compliance with ethical and regulatory requirements. The successful coordination among clinical teams and the active involvement of participants and their informal caregivers have contributed to the efficient progression of the study.

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