

THIS DOCUMENT IS EXTRACTED FROM THE FULL DELIVERABLE, AS THE ORIGINAL DELIVERABLE CONTAINS CONFIDENTIAL INFORMATION FOR THE COURSE OF THE PROJECT. THE FULL DELIVERABLE CONTENT WILL BE PUBLISHED AFTER THE END OF THE PROJECT.



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



WP5: CAREPATH clinical investigation D5.3: Midterm recruitment report

Contractual Date of Delivery to the EC: 31 October 2023, then extended to 30 June 2024 with the agreement of the EC Project Officer (PO)

Actual Date of Delivery to the EC: 30 June 2024

Participant(s): ⁸CITSI, ¹EXYS, ³SKB, ⁵UHCW, ⁶SESCAM

Author(s): ⁸Oana Cramariuc, ⁸Cristiana Ciobanu, ⁸Tudor Teodorescu, ¹Jaouhar Ayadi, ¹Angelo Consoli, ³Wolfgang Schmidt-Barzynski, ³Antje Steinhoff, ⁵Tim Robbins, ⁵Harpal Randeva, ⁵Sonia Kandola, ⁵Natassia Garton, ⁶Pedro Abizanda, ⁶Angel Jesus Saez

Type (P-prototype, R-report, O-other, ORDP-Open Research Data Pilot, DEM-Demonstrator, ET-Ethics): R

Dissemination level (PU-Public, CO-Confidential): PU

Version: 1v4

Total number of pages: 16



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945169.

THIS DOCUMENT IS EXTRACTED FROM THE FULL DELIVERABLE, AS THE ORIGINAL DELIVERABLE CONTAINS CONFIDENTIAL INFORMATION FOR THE COURSE OF THE PROJECT. THE FULL DELIVERABLE CONTENT WILL BE PUBLISHED AFTER THE END OF THE PROJECT.

Executive Summary

The aim of the present document is to present an overview of the recruiting process and recruited subjects in each clinical site. Potential recruiting problems and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment are also part of this deliverable. The current document is a first version of the deliverable which is outlining the preliminary recruitment efforts at all pilot sites. These were made in preparation of the ethical clearance for the TVU and the clinical investigations. We are also presenting the randomized patient inclusion methodology which will be applied for the clinical investigation.

The current approval for the clinical studies in Spain, granted to SESCOAM, and the TVU approval in the UK granted for UHCW, is expected to facilitate and speed up the approval process in all countries. This will allow to actively involve patients and update in a next step the current deliverable.

THIS DOCUMENT IS EXTRACTED FROM THE FULL DELIVERABLE, AS THE ORIGINAL DELIVERABLE CONTAINS CONFIDENTIAL INFORMATION FOR THE COURSE OF THE PROJECT. THE FULL DELIVERABLE CONTENT WILL BE PUBLISHED AFTER THE END OF THE PROJECT.

Table of contents

1	INTRODUCTION	5
1.1	PROJECT INFORMATION	5
1.2	DOCUMENT SCOPE AND STRUCTURE	5
2	SUMMARY OF STUDY PROTOCOL	6
2.1	TVU STUDY	6
2.2	CLINICAL INVESTIGATION WITH A MEDICAL DEVICE CLASS IIA	7
3	METHODOLOGY FOR THE RANDOMIZED PATIENT INCLUSION	9
	<i>Inclusion Criteria</i>	9
	<i>Exclusion Criteria</i>	9
	<i>Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors.</i>	10
4	PATIENT RECRUITMENT AT THE CLINICAL SITES	12
4.1	SKB IN GERMANY	12
4.2	CITST IN ROMANIA	12
4.3	SESCAM IN SPAIN	12
4.4	UK	12
5	CONCLUSIONS	14
6	REFERENCES	15
7	DOCUMENT HISTORY	16