Virtual Coaching Activities for Rehabilitation in Elderly

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D1.5 Study Design

Extended summary

This document describes the Study Design, i.e. the implementation plan for the technical and clinical testing of the **vCare** solution.

The **vCare** testing approach is composed of three different phases:
- The Tech Labs Phase
- The Living Labs Phase
- The Pilot Tests Phase

This division in phases aims at testing the system incrementally focusing on available requirements and their technical translation, integration between components, usability and user-friendliness though a continuous involvement of patients and caregivers.

The initial description of the project identifies as one of its key ambition to "involve users as main drivers for the innovation at all stages of the project". Participatory Design activities, i.e. users involvement throughout "thinking and testing" activities, have been planned throughout the project with a direct participation of the final users (patients and clinical staff) which increases at each phase.

The report builds upon inputs provided by the deliverables of different work packages. It provides guidance on how to perform the validation of the ICT-based Virtual Coaching system during the forthcoming phases (Living Lab and Pilot). The reports on Tech Labs, Living Labs, and Pilot Tests activities need thus to be read with this document as core reference.

BACKGROUND

This report provides guidelines and operational procedures to test the technical and clinical functionalities of **vCare**. It is structured in three phases according to the three sequential tasks foreseen for the technical and clinical validation (covering an overall period of time of 22 months):
- Study Design in Tech Labs
- Study Design in Living Labs
- Study Design in Pilot Tests

The figure below describes in a schematic way the process and the methods used to engage end-users in those different phases, focusing specifically on the technical and clinical functionalities and the vCare solution reliability acceptability and usability.
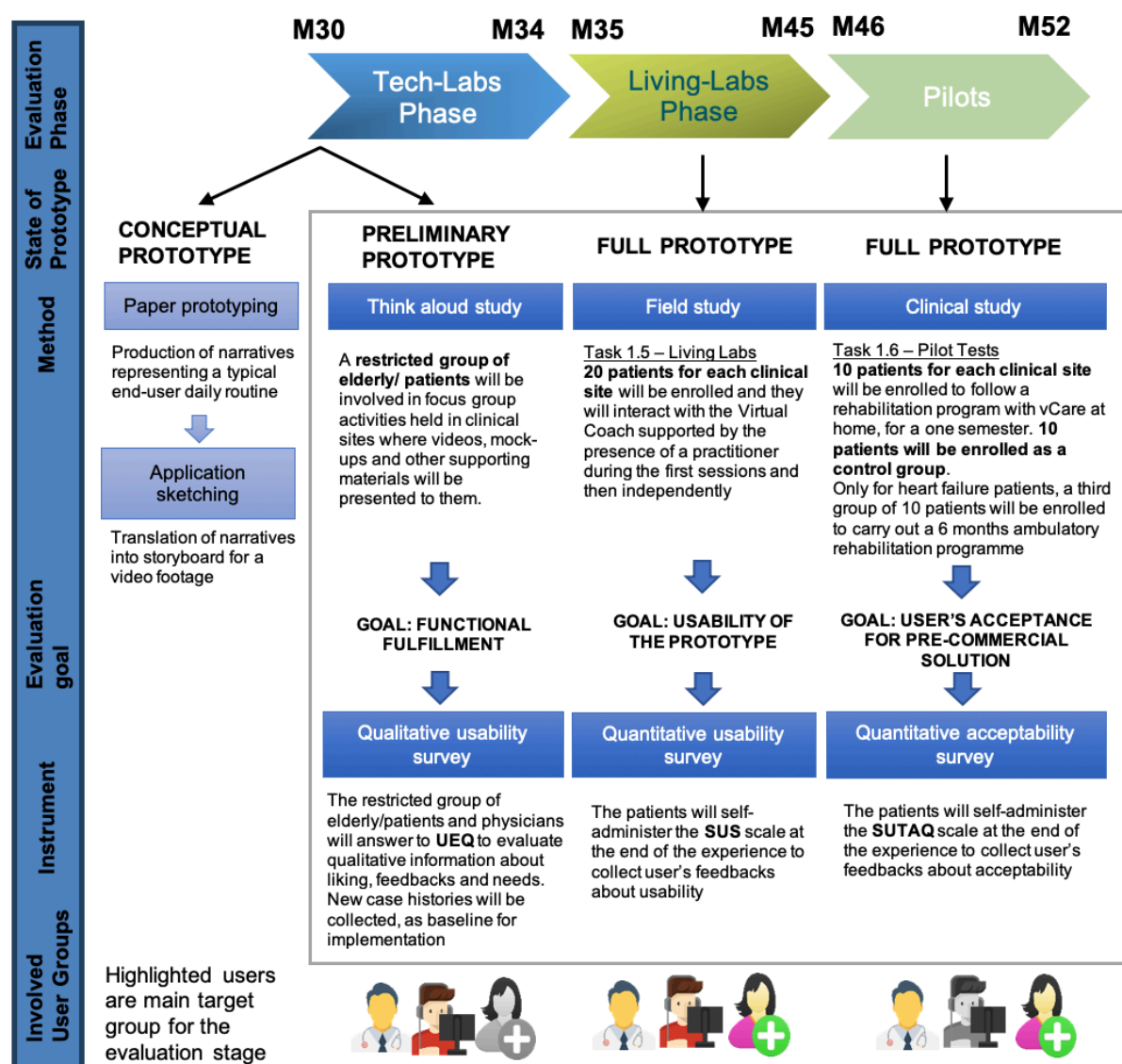
Figure - Phases of the vCare testing procedure and Participatory Design activities

TECH LAB PHASE – STUDY DESIGN

During the Tech Lab Phase, the vCare system will be tested by technical partners, with the involvement of clinical professionals in co-creation and evaluation of the solution. This phase aims to validate and consolidate the **traceability** between:

a) clinical needs and patient profiles;
b) clinical needs and narratives;
c) clinical needs and technical Requirements/Services.

The plan for testing the system functionalities is based on the sole Activities. For each rehabilitation Activity, a validation test is defined: It describes all the steps necessary to obtain an objective proof of the technical implementation of the Functional Requirements (and related Services).

In parallel, end-user's perspective is also captured: The clinical partners have created original supporting material such as videos and booklets featuring the everyday life of a

patient living with a virtual coach. Interviews and- if possible- focus groups are organized to collect the feed-back of the final users while a UEQ questionnaire will be used to collect user experience in order to verify the system fulfils all the functional requirements.

LIVING LAB PHASE – STUDY DESIGN

In the Living Lab Phase, the system will be tested for the first time directly by the vCare final users (patients) in a "controlled environment" with the supervision of members of the clinical staff. In this phase the **focus is on the overall Clinical Pathway** for **adaptation** purposes.

The implementation methodology of the Living Labs tests is grounded on the Medical Use Cases. Each patient is expected to interact with the Virtual Coach performing one or more Use Cases, according to his/her clinical needs. Guidelines to evaluate system adaptation were divided into two categories based on either Pathway or Behaviour. The rules and mechanisms to be applied for each Activity which were described in a previous deliverable (D1.3) were used to build those guidelines.

Feedbacks concerning the system usability will be collected from end-users through a SUS scale.

PILOT TESTS PHASE – STUDY DESIGN

In the Pilot Test Phase, the implemented and tested system will be clinically validated at users' homes to **measure the impact** of the new vCare rehabilitation coaching service. This phase is driven by clinical practice.

A **clinical protocol** for the final validation of the system has been drafted. Groups of patients will be enrolled for each clinical site and will follow the rehabilitation program with vCare at home during a six months period. In addition to clinical protocols, clinical project objectives have been detailed in order to check the feasibility for the elaboration of a **clinical KPI dashboard**.

At the end of this phase, the Service User Technology Acceptability Questionnaire (SUTAQ) will be administrated to patients in order to evaluate user's feedbacks about acceptability of the proposed solution. This information could become part of a potential Participatory Design of a pre-commercial solution.