CLINICAL ENGAGEMENT IN CO-DESIGN AND VALIDATION

NESTORE FINAL WORKSHOP, 25/02/2021

CASA CURA POLICLINICO

- CCP is a fully integrated **multi-specialty Clinical Centre** (148 beds), accredited by the Italian National Health System
- CCP provides both inpatient and outpatient services, mainly directed to **neurological patients**.
- These services improve **rehabilitation care pathways**, responding to an integrated and multidisciplinary approach
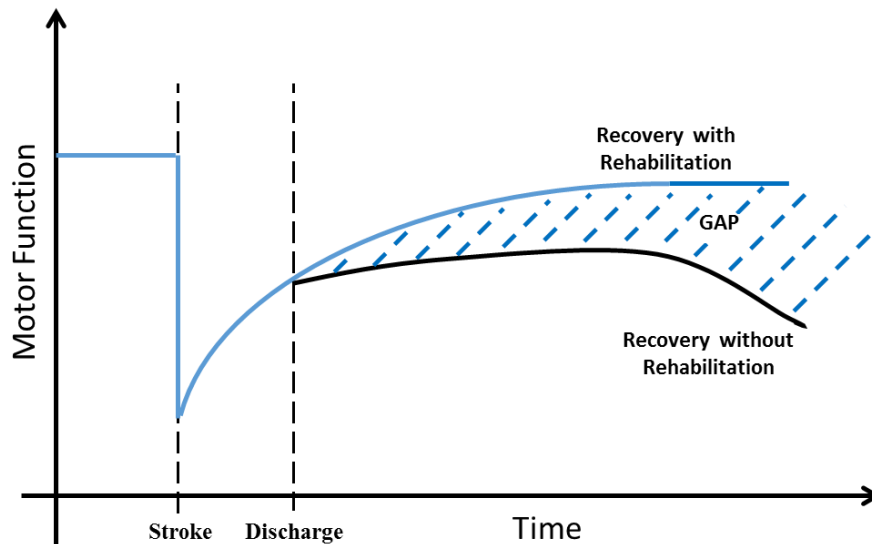
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BACKGROUND
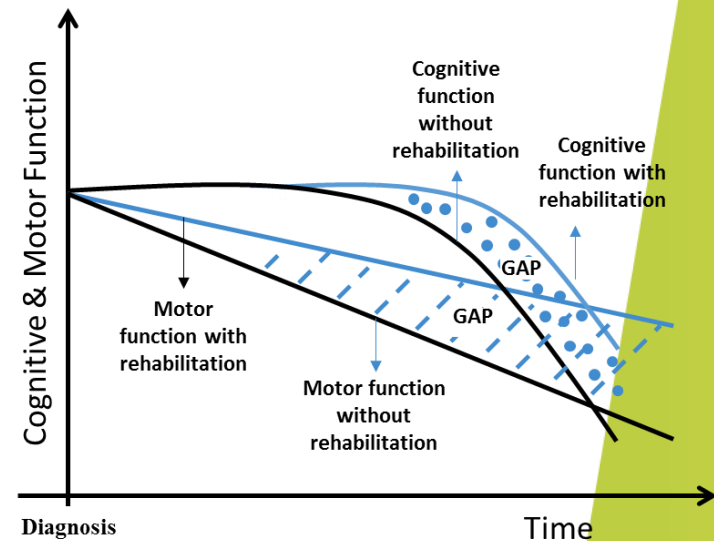
Often the continuity of the rehabilitation process interrupts with the transition to the home environment.

Stroke Recovery Model

Progression in Parkinson's disease

Modified from *Langhorne, Bernhardt, and Kwakkel 2011*

Modified from *Nocera and Hackney M E 2015*

DESIDERED SITUATION IN REHABILITATION

Clinical Setting

Post Stroke Cognitive Decline

inpatients

Post Heart Attack Physical Disabilities

Orthopedical interventions

?

outpatients

General Practitioner

Rehab Center

Personalized Rehabilitation Program + **Setting Virtual Coach**

Neurologist/Physiatrist Social Worker, Physiotherapist, Neuropsychologist, Case manager (nurse)

Home Environment

Rehabilitation Program at Home + **Virtual Coach Activity**

Continuity of Care

Monitoring

Treatment Optimization

Coaching

Conditions

Habits

Context

4

KEY ASPECTS OF VCARE

STROKE

PARKINSON'S DISEASE

HEART FAILURE

HEART ATTACK

Enhancement of Quality of Life

Individual Clinical Pathway

Basis for **Rehab** *Activities*

Patient Empowerement

Encouraging Self-Management

Continous Personalization

Pathways

Treatment

Empower

Alert

Automated Adaptation

REHABILITATION ACTIVITIES

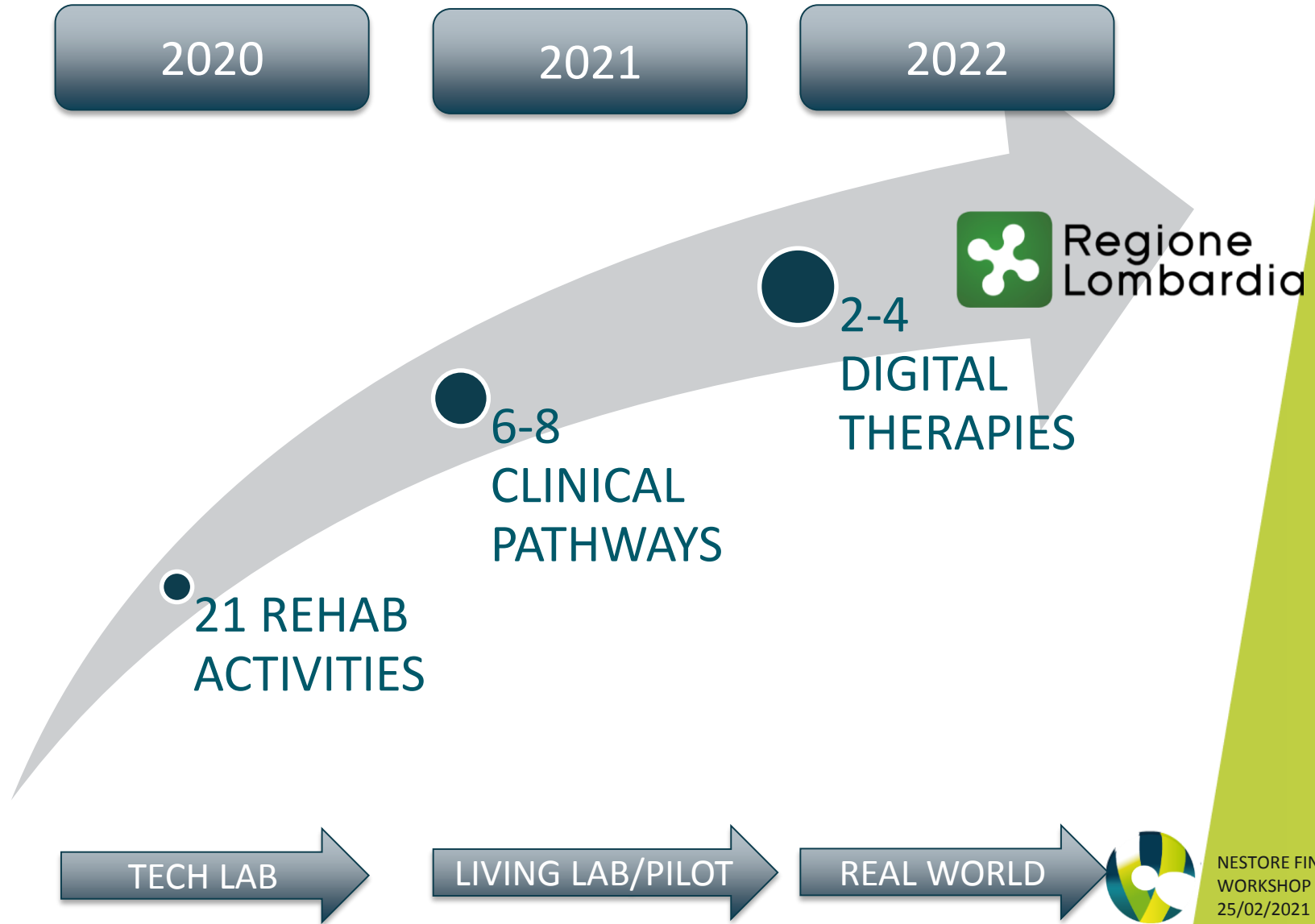| A #	Activity (A)	Pathology	Needs
A-1	Home-based motor activities	SD, PD	Physical therapy
A-2	Coaching for an active lifestyle	SD, PD	Physical therapy
A-3	E-learning	SD, PD, HF, IHD	Physical therapy, Cognitive training
A-4	Home based cognitive games	SD, PD	Cognitive training
A-5	Fun supporting activities	SD, PD	Cognitive training
A-6	Monitoring indoor	SD	Risk Factor Modification
A-7	Safety tips	SD	Risk factor Modification
A-8	Monitoring mood	SD, PD, IHD	Emotional and Social rehabilitation
A-9	Monitoring Pain and sleep	SD	Pain
A-10	Vocal Exercises	PD	Speech and swallowing therapy
A-11	Falls Prevention	PD	Risk Factor Modification
A-12	Daily Motor Activity	HF	Physical therapy
A-13	Aerobic Physical Activity	HF, IHD	Physical therapy
A-14	Resistance training	HF	Physical therapy
A-15	Medication intake support	PD, HF, IHD	Pharmacological intervention
A-16	Vital stats control	HF	Monitor Vital signs
A-17	Weight control	HF, IHD	Risk Factor Modification
A-18	Smoking cessation activity	HF, IHD	Risk Factor Modification
A-19	Anxiety and depression reduction	HF	Emotional and Social rehabilitation
A-20	Walking physical activity	IHD	Physical therapy
A-21	Alcohol Reduction	IHD	Risk Factor Modification

THE APPROACH TO VALIDATION
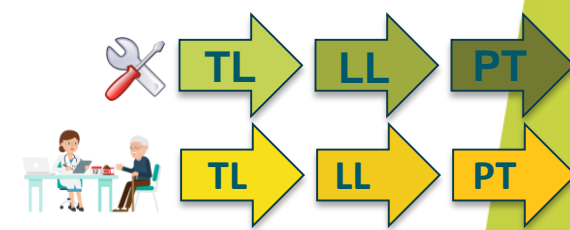
Sequence of **tasks** in which to "involve users as main drivers for the innovation at all stages of the project"
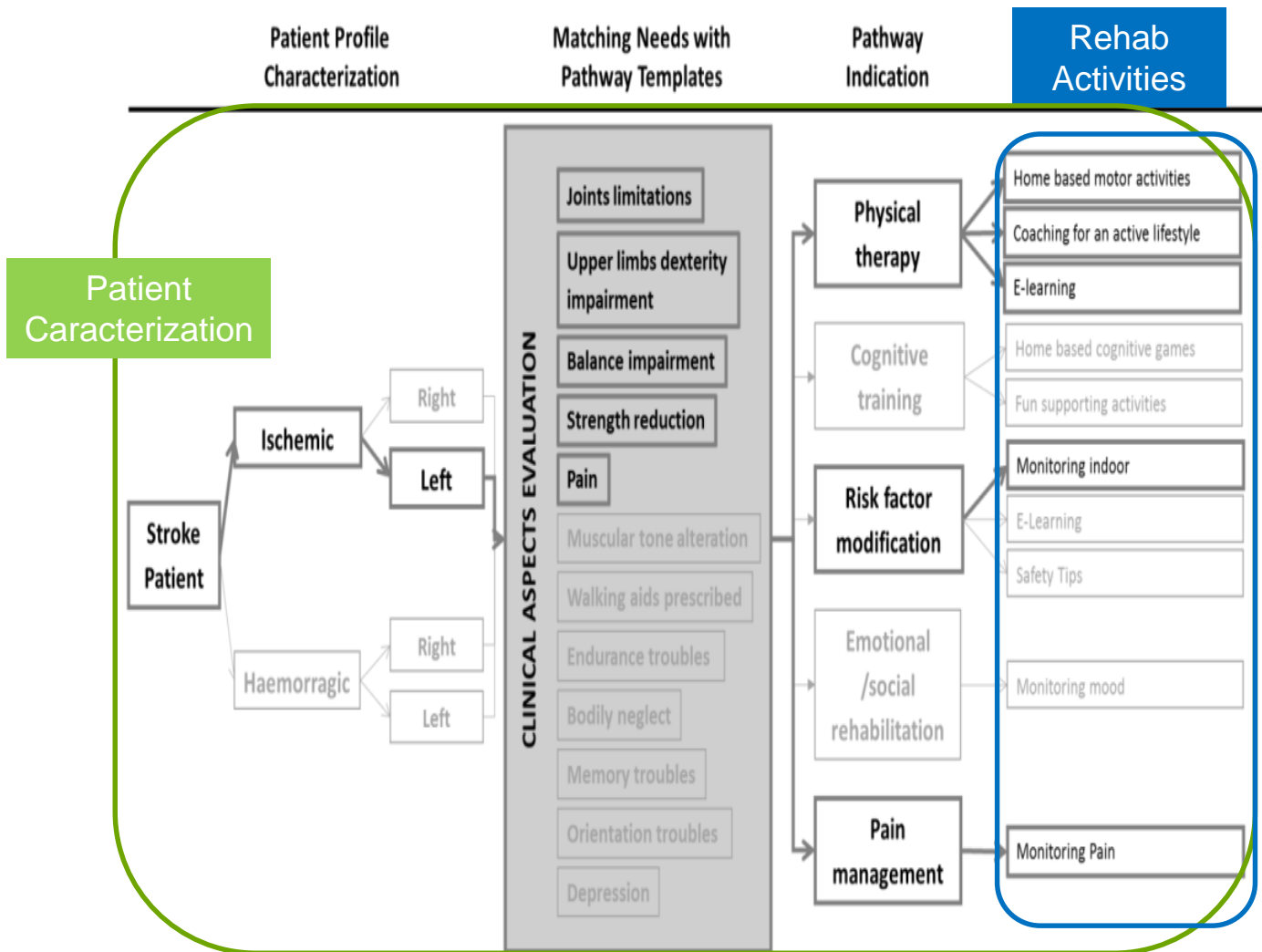
T1.4	**T1.5**	**T1.6**
M30 – M34	M35 – M45	M46 – M52

Professional

Tech-Lab Phase — Driven by technical requirements

Living Lab Phase — Driven by Use Cases / Driven by feedbacks rollout

Pilot Test Phase — Driven by real life experience

Patient

Tech-Lab Phase — Driven by co-design approach

Living Lab Phase — Driven by experience in lab

Pilot Test Phase — Driven by final environmental living
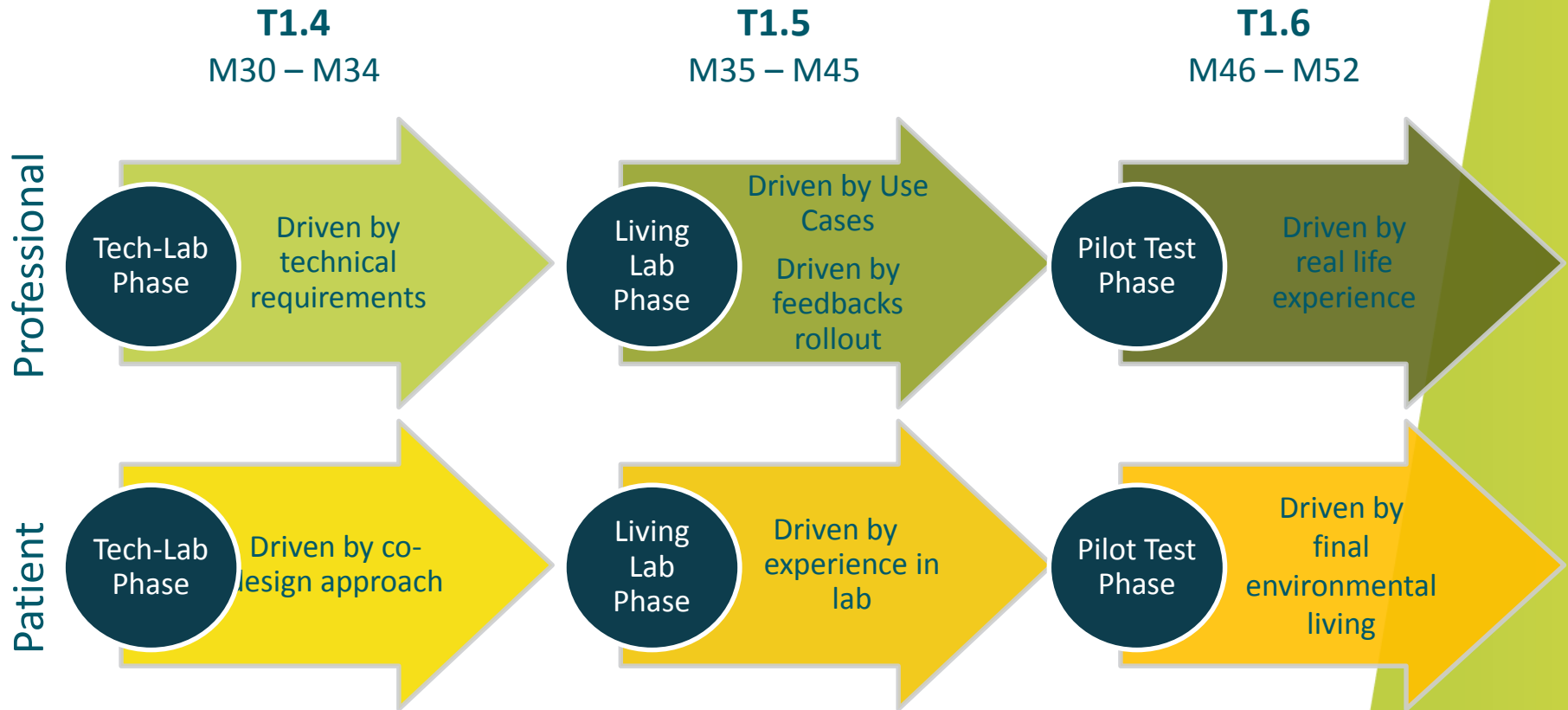
TOWARD EXPOLITABLE OUTCOMES

2020

2021

2022

Regione Lombardia

2-4 DIGITAL THERAPIES

6-8 CLINICAL PATHWAYS

21 REHAB ACTIVITIES

TECH LAB

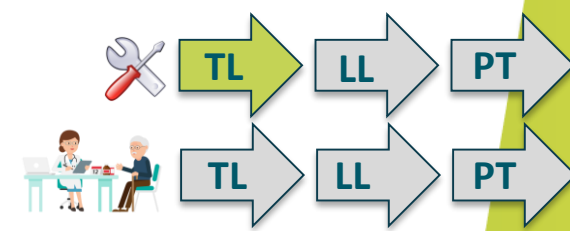LIVING LAB/PILOT

REAL WORLD
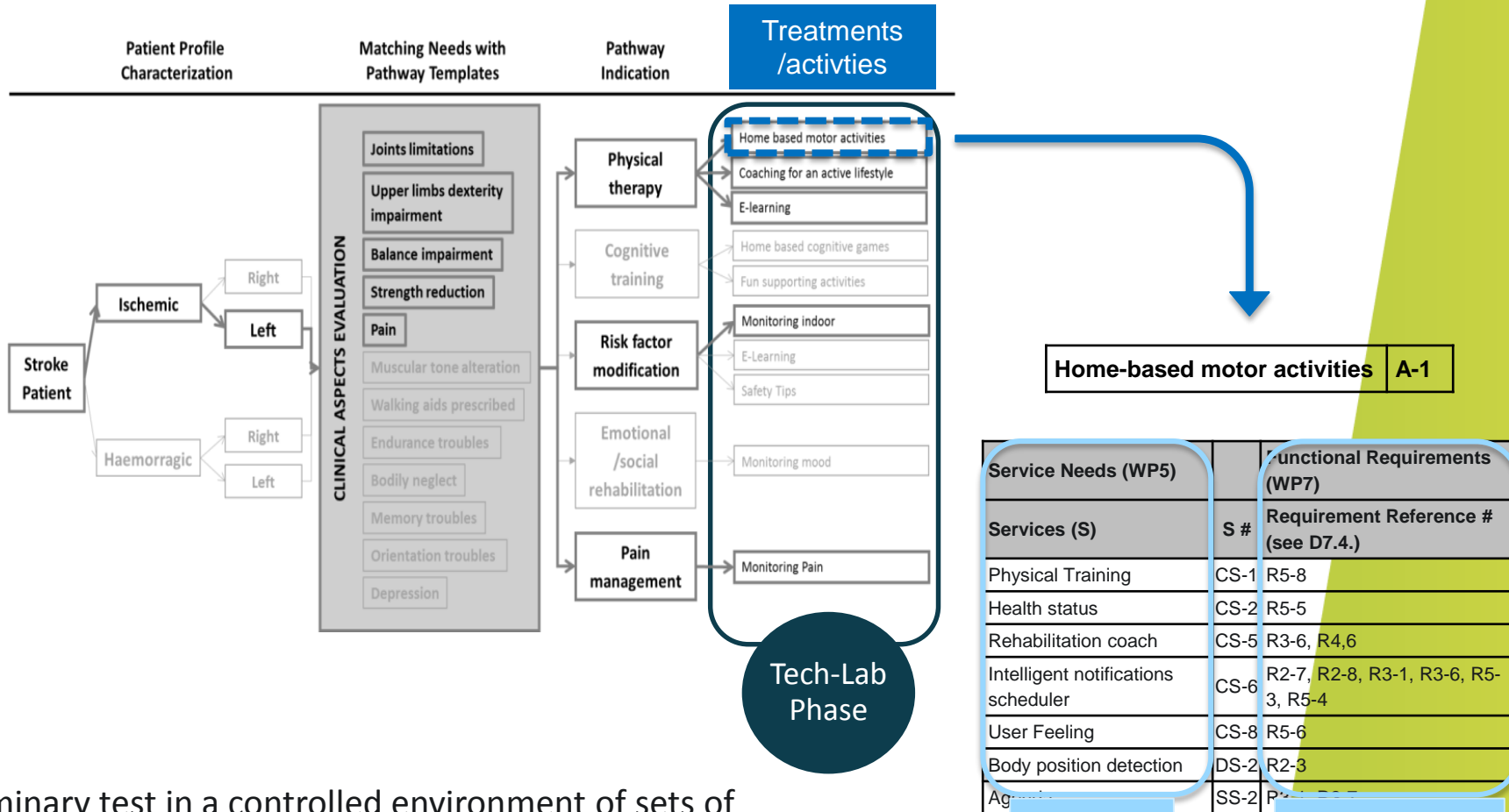
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CLINICAL PATHWAYS: THE STROKE CASE

TECH LAB PHASE

CLINICAL PATHWAY from D1.4

Treatments /activties

Home-based motor activities | A-1

Tech-Lab Phase

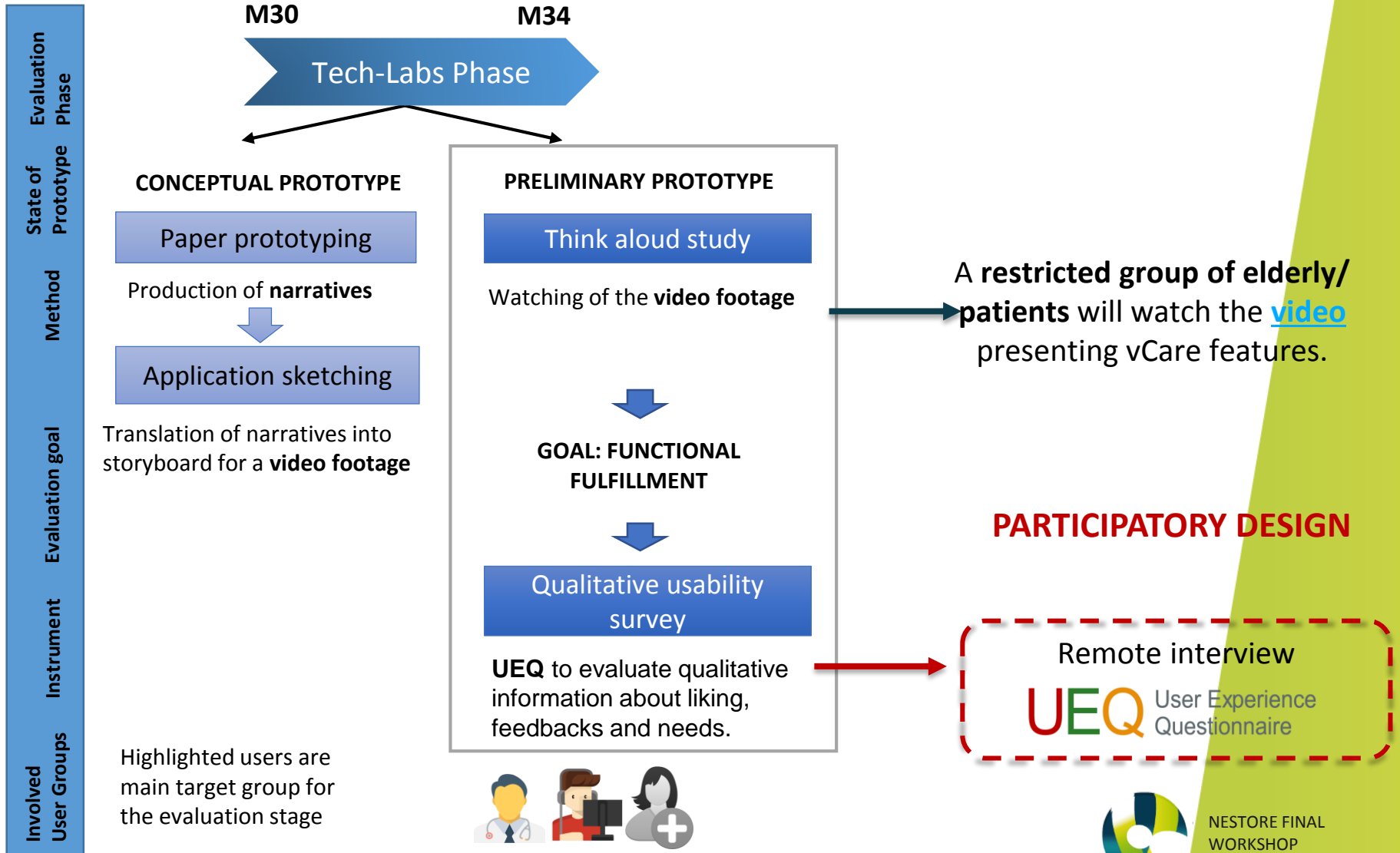| Service Needs (WP5)		Functional Requirements (WP7)
Services (S)	S #	Requirement Reference # (see D7.4.)
Physical Training	CS-1	R5-8
Health status	CS-2	R5-5
Rehabilitation coach	CS-5	R3-6, R4,6
Intelligent notifications scheduler	CS-6	R2-7, R2-8, R3-1, R3-6, R5-3, R5-4
User Feeling	CS-8	R5-6
Body position detection	DS-2	R2-3
Ag...	SS-2	R...

Services

Functional requirements
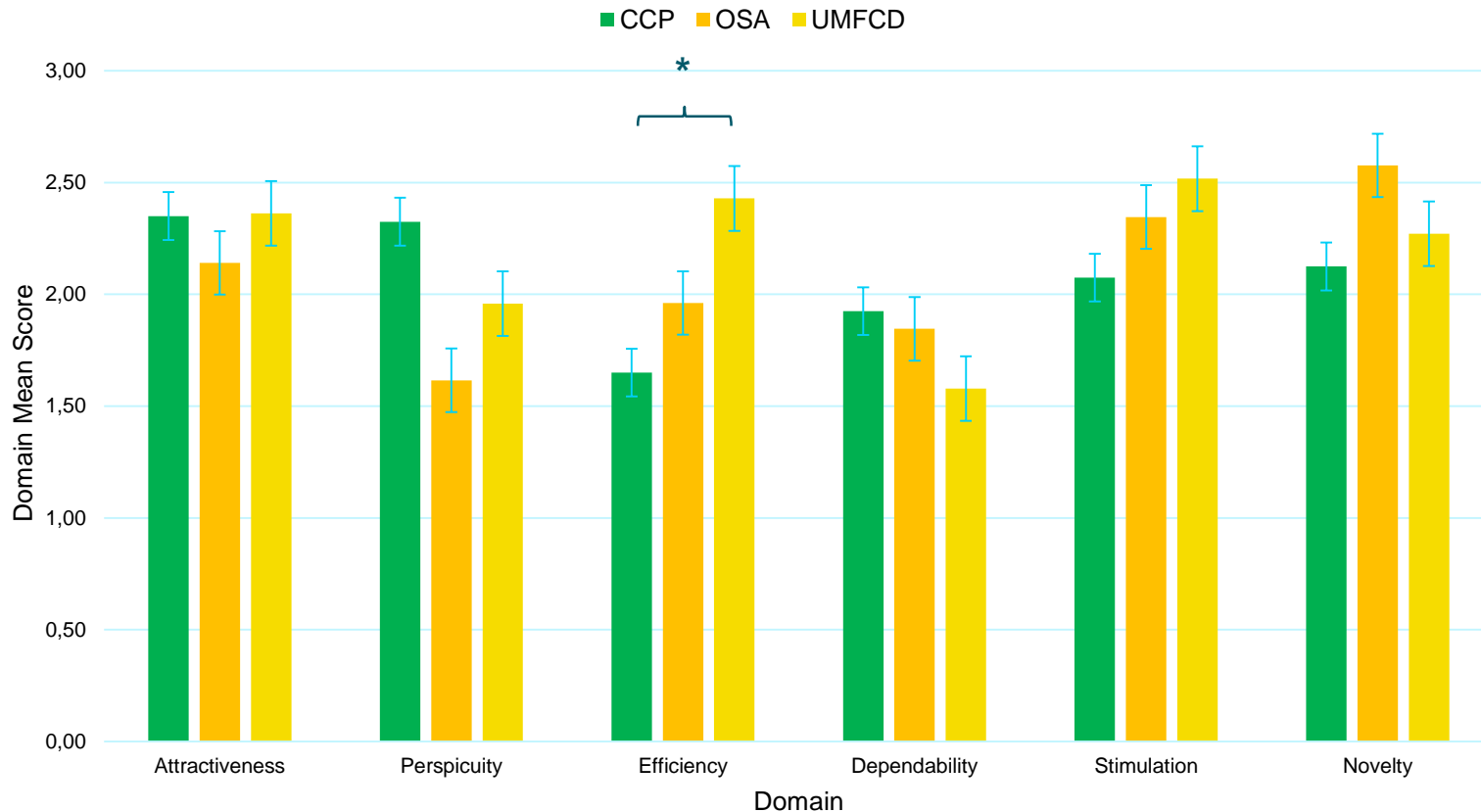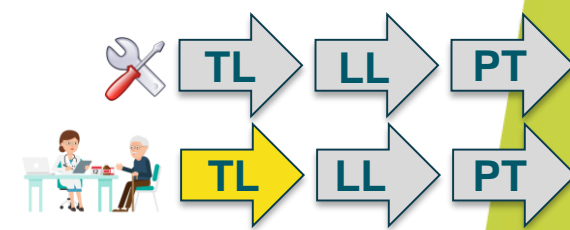
Preliminary test in a controlled environment of sets of REQUIREMENTS and related SERVICE(S), grouped by **ACTIVITIES**
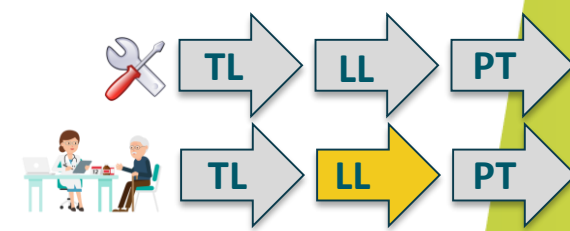
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TECH LAB PHASE

M30   **M34**

Tech-Labs Phase

Evaluation Phase	

CONCEPTUAL PROTOTYPE

Paper prototyping

Production of **narratives**

Application sketching

Translation of narratives into storyboard for a **video footage**

Highlighted users are main target group for the evaluation stage

PRELIMINARY PROTOTYPE

Think aloud study

Watching of the **video footage**

GOAL: FUNCTIONAL FULFILLMENT

Qualitative usability survey

UEQ to evaluate qualitative information about liking, feedbacks and needs.

State of Prototype

Method

Evaluation goal

Instrument

Involved User Groups

A **restricted group of elderly/ patients** will watch the **video** presenting vCare features.

PARTICIPATORY DESIGN

Remote interview

UEQ User Experience Questionnaire
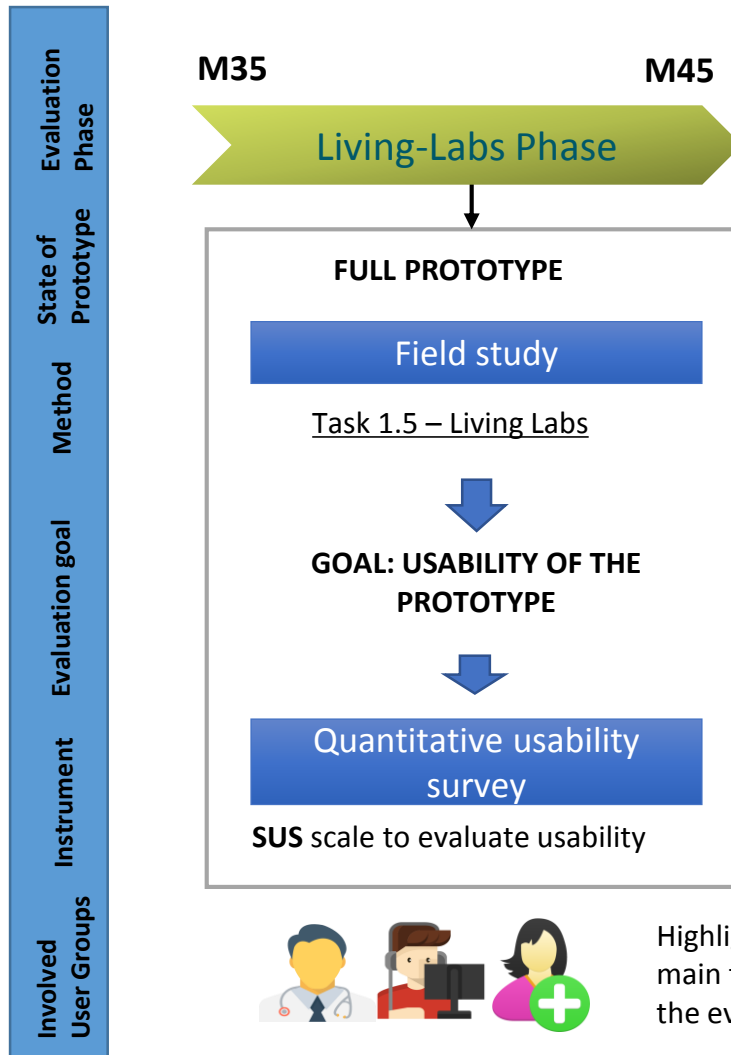
RESULTS FROM UEQ

A One-Way ANalysis Of VAriance (ANOVA) was carried out to check if the domain means differ significantly among the three clinical centres. A statistically significant difference between groups was found only in the Efficiency domain.
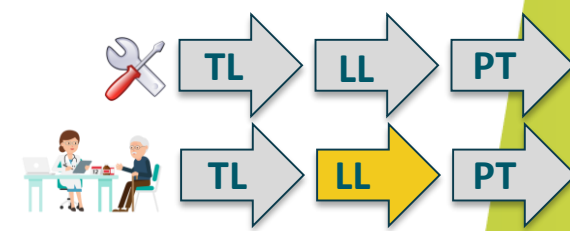
LIVING LAB PHASE

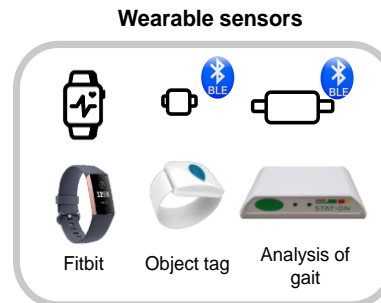Testing of the system by the vCare **final users** in a *"controlled environment"*
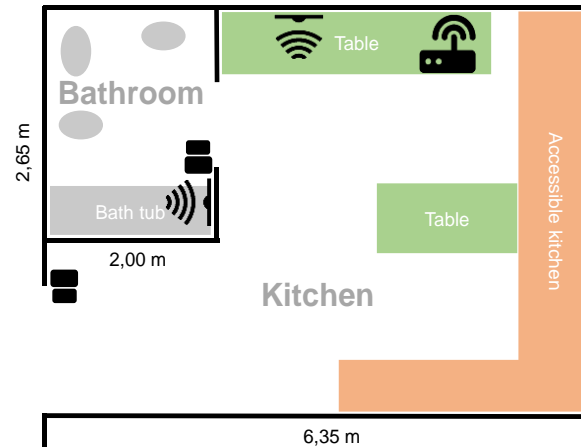
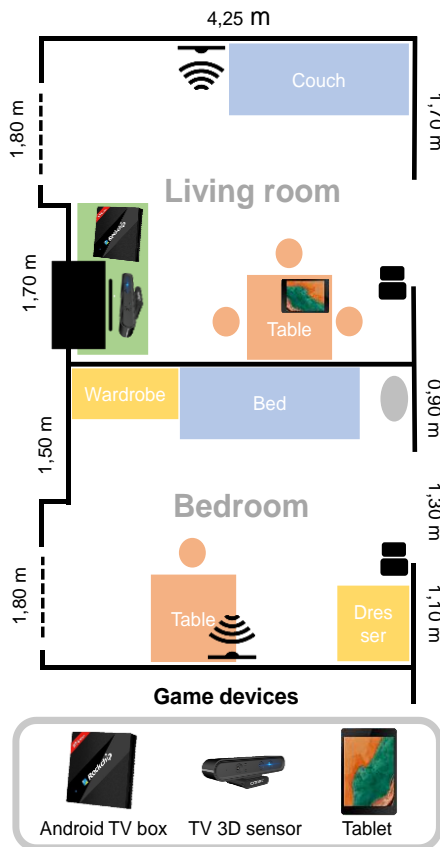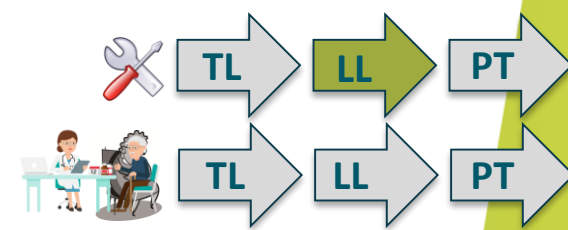|	
Evaluation Phase	**M35** **M45**
	Living-Labs Phase
State of Prototype	**FULL PROTOTYPE**
Method	Field study
	Task 1.5 – Living Labs
Evaluation goal	**GOAL: USABILITY OF THE PROTOTYPE**
Instrument	Quantitative usability survey
	SUS scale to evaluate usability
Involved User Groups	Highlighted users are main target group for the evaluation stage

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WORKSHOP
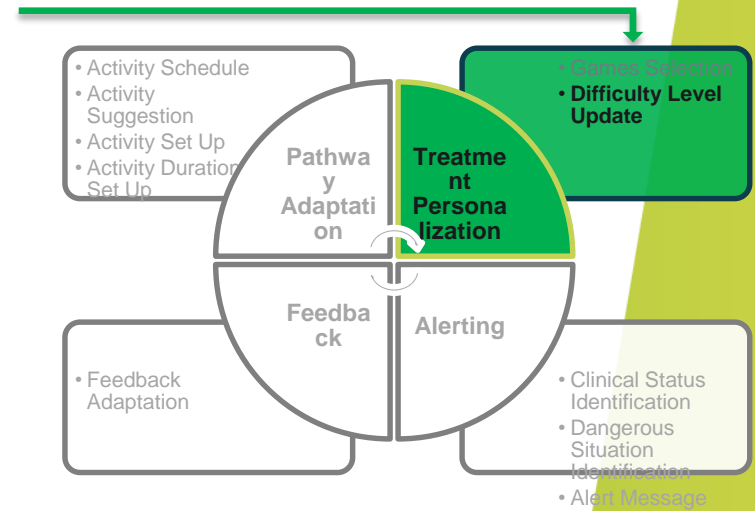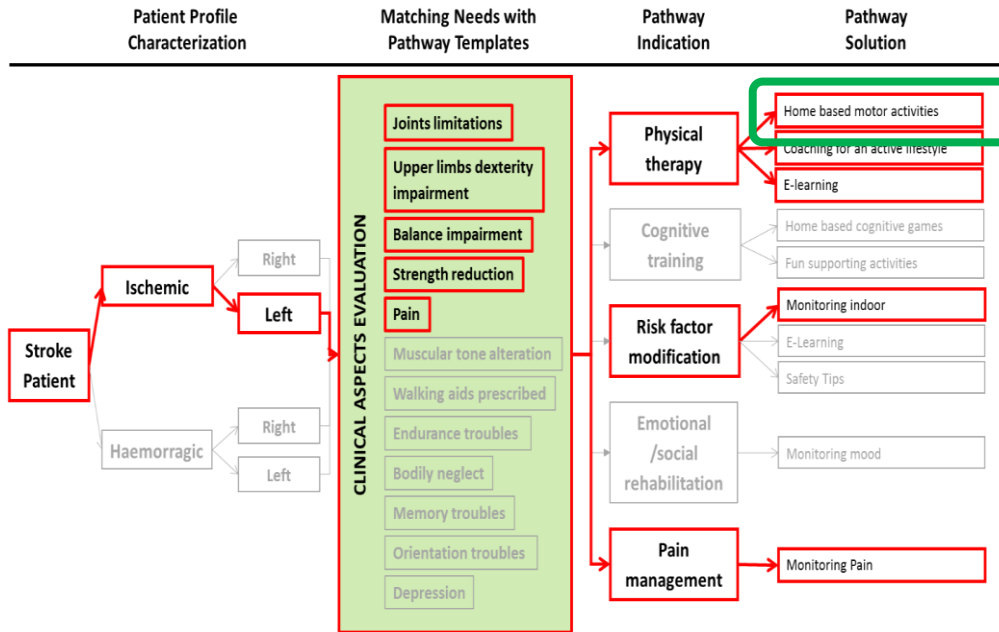25/02/2021

LIVING LAB PHASE

*Living Labs can be defined as **Ecological Systems** in which users evaluate new ICT-solutions experimenting and testing them in a familiar usage framework and within a real-world context[2].*

Smart - Home sensors

Presence sensor

Door sensor

Gateway

Wearable sensors

Fitbit   Object tag   Analysis of gait

Game devices

Android TV box   TV 3D sensor   Tablet

Living room
- 4,25 m
- 1,80 m
- 1,70 m
- 1,70 m
- Couch
- Table

Bedroom
- 1,50 m
- 1,80 m
- Wardrobe
- Bed
- 0,90 m
- Table
- Dresser
- 1,30 m
- 1,10 m

Bathroom
- 2,65 m
- Table
- Bath tub
- 2,00 m

Kitchen
- Accessible kitchen
- 4,50 m
- Table
- 6,35 m

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LIVING LAB PHASE - EXAMPLE

Stroke - First Narrative: Mrs. Maria – Use cases #1

DIFFICULTY LEVEL UPDATE

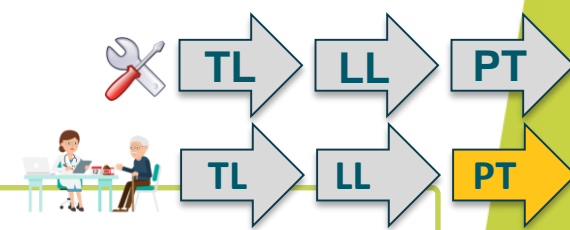| **Rules** (D1.3)	**Test** (D1.5)	**KPI** (D1.7)
if (Game #N Score) Week > tGNS+5% tGNS → tGNS = tGNS +(5% tGNS) **if** (Game #N Score) Week < tGNS-5% tGNS → tGNS = tGNS -(5% tGNS) **If** tGNS automatically updated for 3 consecutive times → the game level improves	Check on the update of the difficulty level of the task by the vCare system based on the patient's performance computed data.	**Agreement/disagreement** between "**VC** difficulty level automatically adjusted" and "**Therapist** difficulty level change". They must correspond at least in **75%** of cases.

PILOT TEST PHASE (T1.6)

CRT for the final validation of the system

PATIENTS

NEUROLOGICAL

- **Stroke** — 20 patients
  - **10** vCare
  - **10** Conventional Rehab
- **Parkinson's** — 20 patients
  - **10** vCare
  - **10** Conventional Rehab

CARDIOLOGICAL

- **Heart Failure** — 30 patients
  - **10** vCare
  - **10** Conventional Rehab
  - **10** Ambulatory
- **Ischemic Heart Disease** — 20 patients
  - **10** vCare
  - **10** Conventional Rehab

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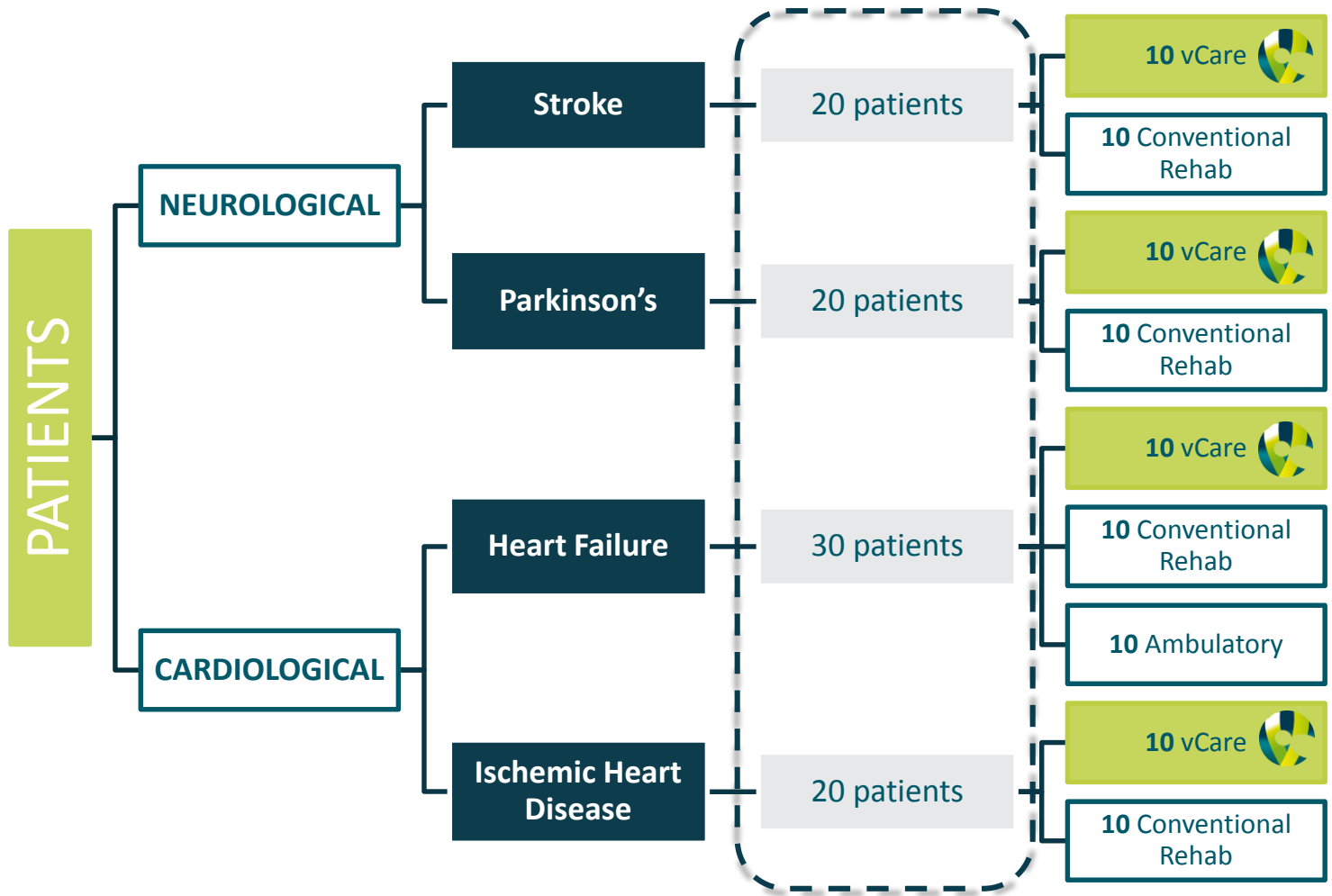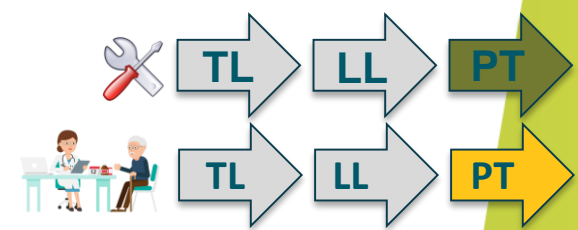
PILOT TEST PHASE

STROKE

Eligibility criteria

•Inclusion criteria

•- Patients who suffered a recent (less than one month) stroke (either ischemic or haemorrhagic) confirmed by CT and/or MRI scan, with a NIH Stroke Scale/Score (NIHSS) score of ≤14, corresponding to a mild-moderate neurological impairment.

•- age ≥65 years

•Exclusion criteria

•- Global aphasia

•- Presence of cognitive impairment (i.e. MMSE≤22)

•- Any evidence of a serious condition that may affect participation in the study (e.g. traumatic brain injury, oncological, hepatic/renal, immune-based, metabolic/endocrine, psychiatric, respiratory, or infective disorders)

•- Unable to understand and comply with the protocol or to give informed consent.

Expected outcomes

Enhancement of QoL

(1) 10% increase of the QoL score (**SF-12**)

(2) 15% increase of the **SF-12 mental sub-score** (Mental Component Summary)

(3) 10% increase of the QoL score on the **Stroke Self-efficacy Questionnaire,** at the end of in-house Pilot Study period (6 months)

1)Risk factor reduction

2)(1) daily number of steps improvement of at least by 10% in six months;

3)(2) time spent exercising improvement of at least by 10% in six months.

Better adherence to care plan at home

(1) Total n°   of subjects that adhere to the Care Plan with *vCare*, raised up to 80%.

(2) N° of rehabilitation treatments, performed autonomously by the patient supported by *vCare*, raised up to 70%.

Personalization and Health promotion

Refinement rate of rehabilitation therapy (exercises and programs) raised up to the 60% of the cases that require a change of treatment.
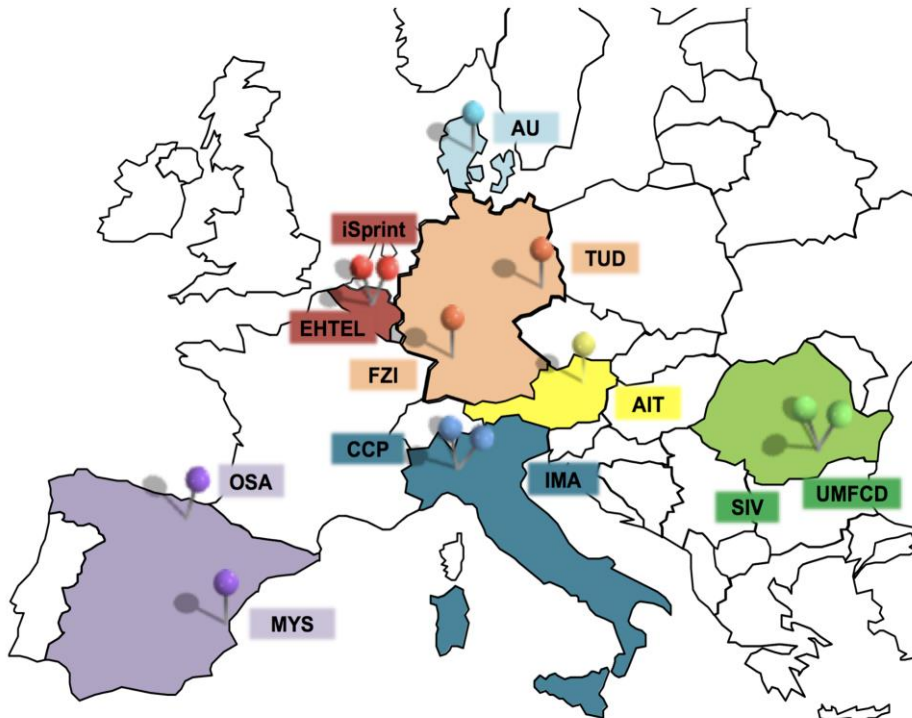
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