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(acronym: RoSNeRa)



The Romanian Spinal Cord Society
(acronym: RoSCoS)

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The importance within STRATIF-AI: from concept to clinical implementation – protocol of study afferent to WP6 in post-Stroke patients' rehabilitation

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REABILITARE MEDICALA SI
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Impact in Neurorehabilitation

Over the past decades, the field of neurorehabilitation has undergone significant expansion, driven by advances in neuroscience, functional imaging, artificial intelligence (AI), robotics, or assistive technologies.

Despite major advances, stroke remains a severe and life-threatening condition, and one of the main causes of long-term disability. This clearly shows that we still need new, more effective approaches.

STRATIF-AI perfectly exemplifies this approach by building bridges between clinical practice, research, and technology, in the service of improving rehabilitation for patients with neurological disabilities.



Impact in Neurorehabilitation

To overcome these challenges, the STRATIF-AI project introduces a hybrid framework that integrates machine learning with multi-level mechanistic models.

These personalized models — known as Digital Twins - provide continuously updated virtual representations of patients, allowing dynamic stratification across all stages of stroke — from prevention to rehabilitation.



Outcome: more efficient rehabilitation and faster social reintegration

Impact in Neurorehabilitation

The international research project STRATIF-AI (2023–2027), entitled “Continuous stratification for improved prevention, treatment, and rehabilitation of stroke patients using digital twins and artificial intelligence (AI),” aims to develop an intelligent digital platform that integrates Digital Twins and AI to enable continuous, personalized stratification and to enhance prevention, treatment, and rehabilitation outcomes in stroke patients.

The project is known by the acronym STRATIF-AI (proposal ID: 101080875-2) and is funded under the European Union’s Horizon Europe Research and Innovation Programme, within the call HORIZON-HLTH-2022-TOOL-12-two-stage.



Impact in Neurorehabilitation

This project presents the conceptual and technological foundations of STRATIF-AI, a Horizon Europe initiative involving 15 partners (universities, hospitals, and research centres) across nine European countries.

The coordinating institution is Linköping University (Sweden), while the national clinical partner is the Teaching Emergency Hospital “Bagdasar-Arseni” (SCUBA), Bucharest, where the institutional coordinator and team lead is Prof. Dr. Gelu Onose.



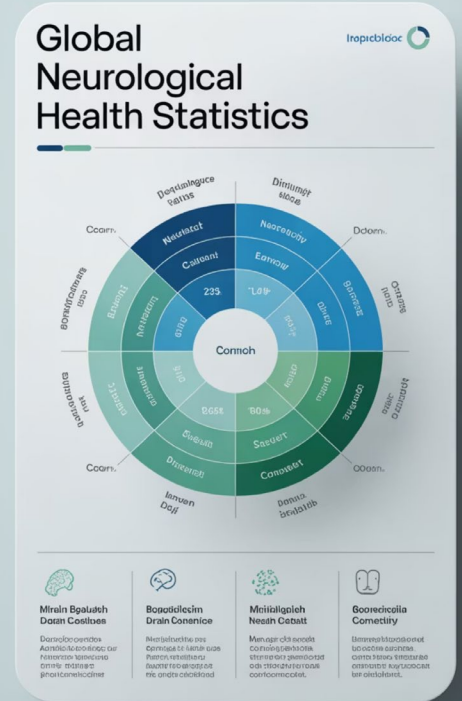
The global context of neurorehabilitation

Globally, approximately 15 million new stroke cases occur each year, according to recent estimates from the World Stroke Organization and the World Health Organization (WHO). A significant proportion of these cases result in death or permanent disability, highlighting the critical need for neurorehabilitation services.

More than 90 million people worldwide live with the consequences of stroke, with a major impact on functional capacity and quality of life.

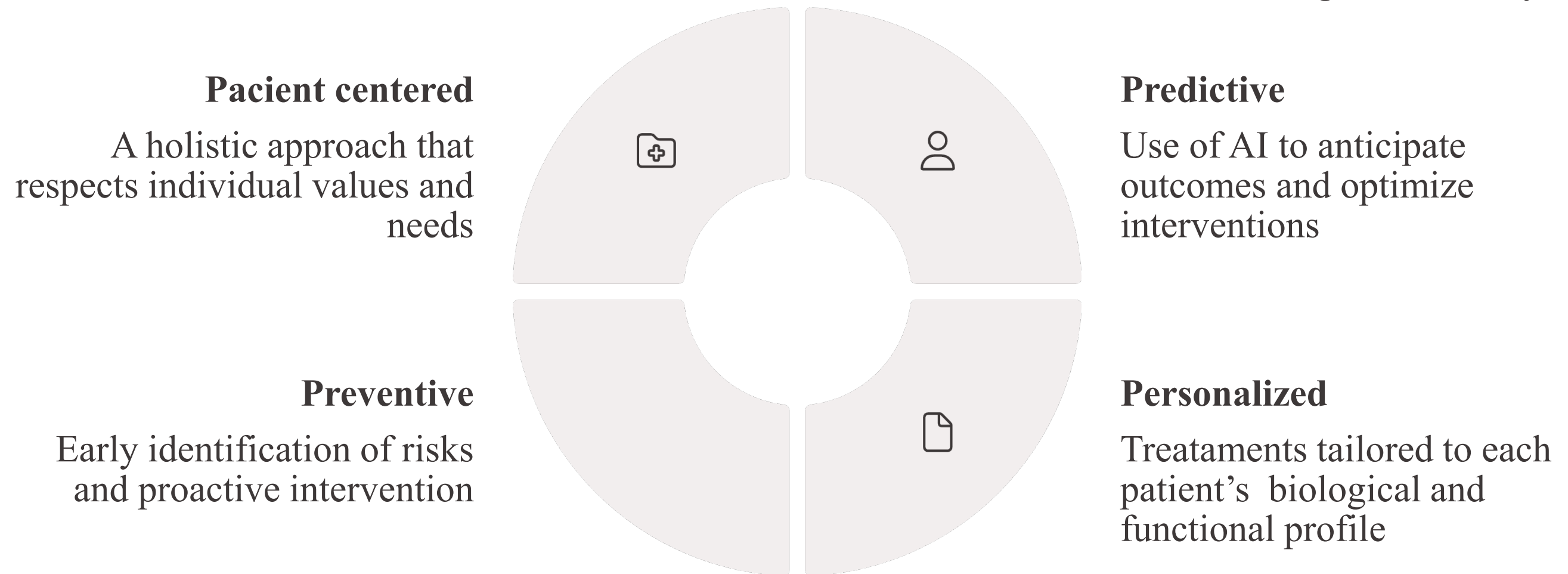
Stroke is the 2nd most common cause of death worldwide. Approximately two-thirds of stroke survivors are discharged with some degree of disability.

In the face of this growing burden of neurological diseases, digital medicine is no longer an option but a necessity. Digital health and telemedicine now enable continuity of care beyond the hospital setting, longitudinal patient monitoring, and improved integration across the acute, subacute, and chronic phases of recovery.



The vision for the future of neurorehabilitation

It aligns with the "**P4 Medicine**" paradigm: predictive, preventive, personalized, and participatory. Personalized neurorehabilitation in the era of digital medicine represents more than a technological evolution — it is a fundamental transformation in how we understand and treat neurological disability.



By integrating translational research, digital innovation, and international collaboration, this vision has the potential to fundamentally transform neurorehabilitation, offering hope and tangible solutions for millions of patients with neurological disabilities.

Current Limitations in Stroke Care/ The Problem We're Solving

Despite best efforts, the current standard of care for stroke patients is constrained by systemic gaps that impede timely, individualized, and evidence-based decision-making through all phases of the disease. Conventional stratification approaches are limited by fragmented data, intermittent clinical assessments and reactive decision-making.

Intermittent Stratification

Patient risk profiling and clinical stratification are performed only at discrete intervals — such as at admission or discharge — rather than continuously throughout the care journey. This means important changes in patient status can go undetected between assessments.

Fragmented Patient Data

Clinical, imaging, functional, and wearable data exist in silos across departments, institutions, and time points. The lack of integration prevents clinicians from forming a holistic, real-time picture of each patient's condition and trajectory.

Delayed or Suboptimal Decisions

Without a unified data platform or intelligent decision-support tool, clinical decisions are often reactive rather than proactive. This leads to delays in intervention and missed opportunities for personalized optimization of treatment and rehabilitation.

The STRATIF-AI Concept

STRATIF-AI is designed to fundamentally transform how stroke patients are monitored, assessed, and treated — shifting from episodic and fragmented care to a continuous, data-driven, and deeply personalized approach.



Continuous Stratification

Rather than static, point-in-time assessments, STRATIF-AI enables real-time and ongoing patient risk stratification across all phases of stroke — from acute onset through rehabilitation and long-term follow-up.



Multimodal Data Integration

The platform consolidates clinical records, neuroimaging, laboratory results, functional assessments, and wearable sensor data into a unified and continuously updated patient profile.



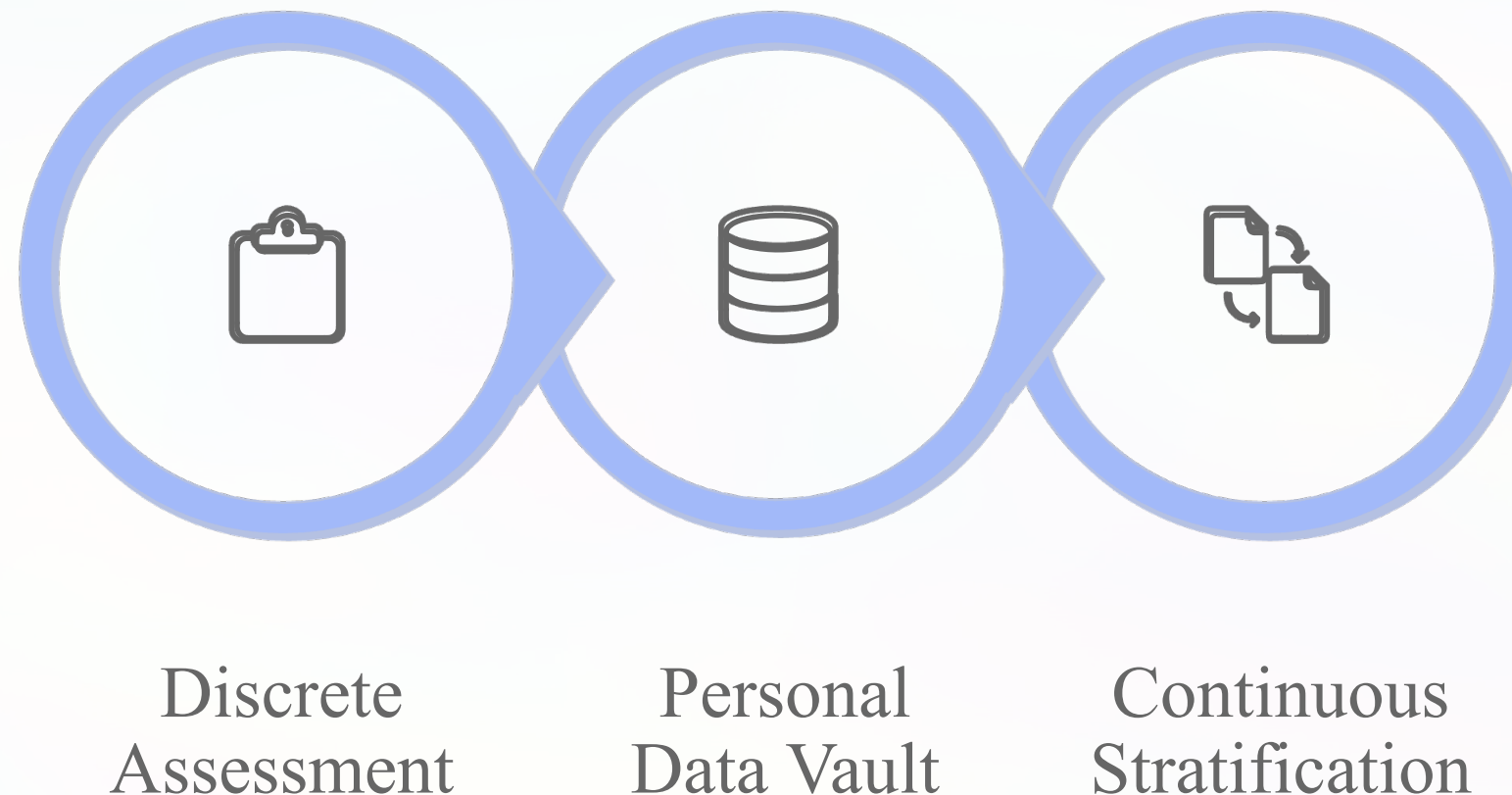
AI-Driven Decision Support

Advanced machine learning algorithms analyze the integrated data to generate actionable, evidence-based recommendations for clinicians — empowering faster, more accurate, and more personalized treatment decisions.



The Concept of Continuous Stratification

Conventional rehabilitation relies on **sporadic assessments** at admission and discharge — stratification decisions quickly become outdated. A new approach is needed that aggregates all patient data continuously and updates clinical decisions in real time.



By combining a **personal data vault (PDV)** with a **hybrid digital twin**, STRATIF-AI enables dynamic, continuously updated stratification across all phases of stroke care — prevention, acute treatment, and neurorehabilitation.

The Digital Twin Concept

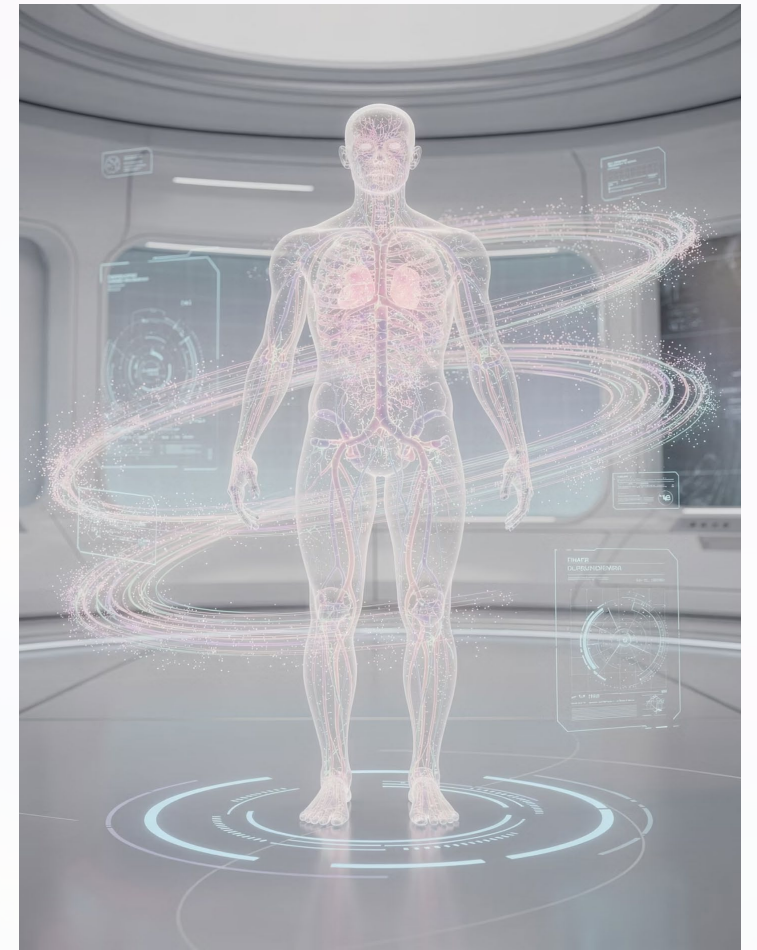
What Is a Digital Twin?

A digital twin (DT) is a virtual model of a real-world system, continuously updated through bidirectional data exchange. In medicine, Digital Twins represent each patient as a dynamic, AI-driven model that supports prediction, monitoring, and personalized care.

The Hybrid Architecture

STRATIF-AI integrates **mechanistic** multi-scale **models** (cerebral haemodynamics, neural recovery, metabolic regulation) with **machine learning** trained on large-scale clinical datasets. This allows to generate real-time, patient-specific Digital Twins — a key innovation of the project.

Coordinated by Linköping University

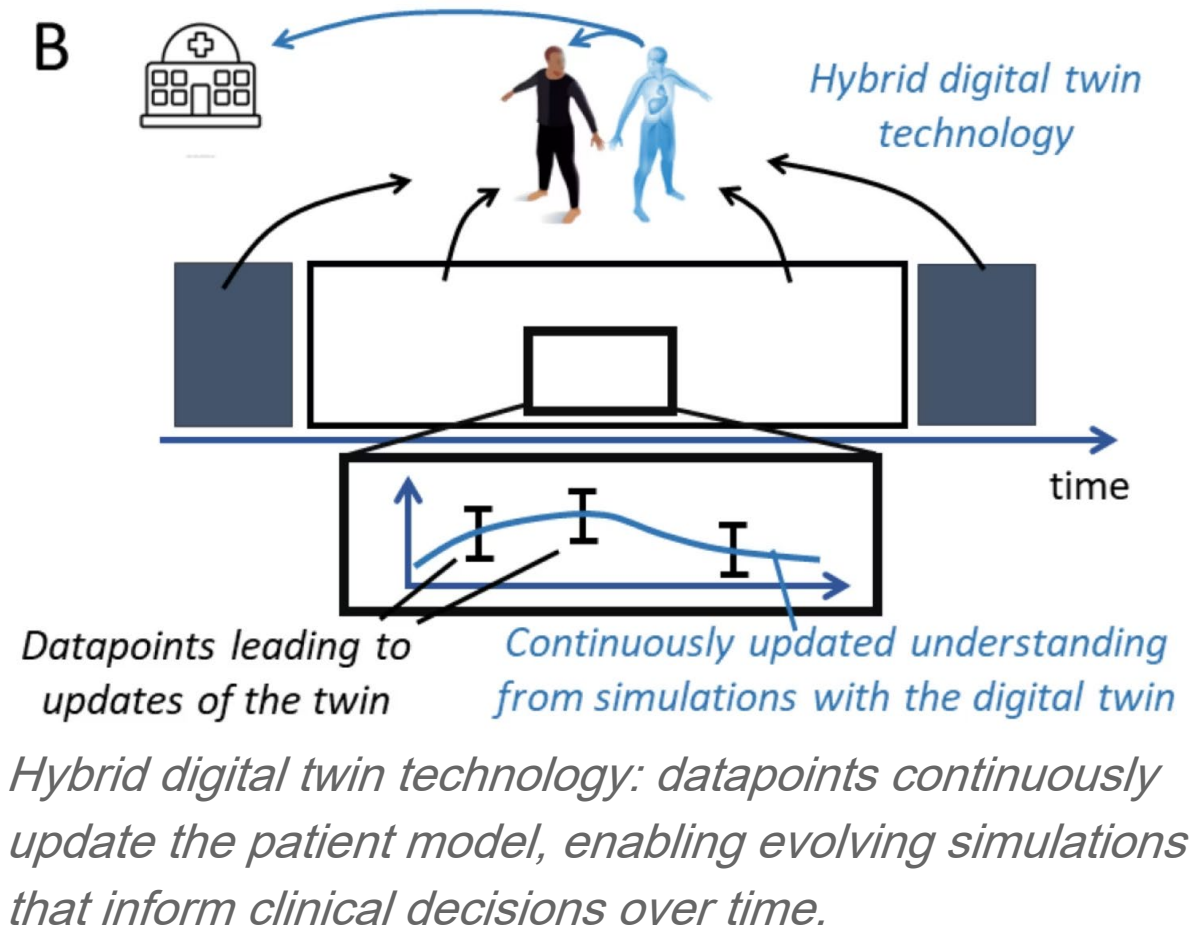


The STRATIF-AI project proposes an original concept of continuous stratification and personalized digital rehabilitation, based on Digital Twins, in the management of stroke patients.

Overall objective: to develop and validate hybrid Digital Twins across all phases of stroke:

- Primary prevention
- Acute treatment
- Post-stroke rehabilitation

The originality lies in the integration of a hybrid architecture combining machine learning algorithms and advanced bioinformatics to create a dynamic, patient-specific representation — the clinical Digital Twin.



Current Stroke Rehabilitation: Clinical Needs Core Challenges

What Rehabilitation Addresses

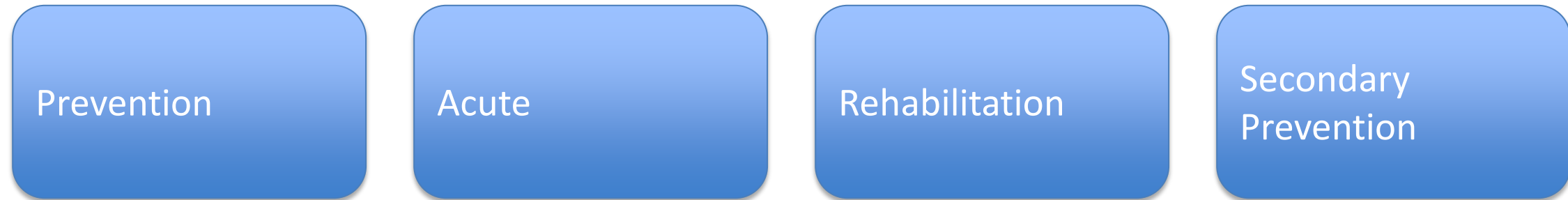
- Motor-sensory recovery and gait training
- Communication and swallowing therapy
- Cognitive and perceptual rehabilitation
- Spasticity, pain, and mood management
- Reintegration into daily and community life

Task-specific therapy should be provided at least **3 hours/day, 5 days/week** — yet many facilities struggle to meet this standard due to limited resources.

Current systems are not optimally structured for prevention, and discrete assessments leave large amounts of patient-generated data underutilized between clinical visits.

Low motivation, unrealistic expectations, and high recovery costs reduce rehabilitation effectiveness.

Continuous Patient Journey



Stroke care does not end in the emergency room. It follows a complex, multi-phase journey—from prevention through acute intervention, rehabilitation and long-term secondary prevention.

STRATIF-AI is designed to support patients across every phase, not just one, providing continuous, intelligent, data-driven care at each transition point.

For the first time... the patient can actually visualize their rehabilitation progress—in real time, across every stage of their journey.

The STRATIF-AI Concept

- STRATIF-AI introduces a fundamentally new paradigm in stroke care: a **continuously updated Digital Twin** for every patient, integrated across the entire care pathway.
- STRATIF-AI is built on three foundational principles that together enable a new paradigm of stroke care — one that is continuous, personalized, and clinically integrated.
- The STRATIF-AI Digital Twin combines multimodal data into a continuously updated patient model, supporting prediction and clinical decision-making.

Continuous Stratification

Risk and recovery are assessed continuously — not at isolated time points, but across all phases of care — enabling clinicians to act based on the most up-to-date patient status.

Digital Twin Follows the Patient

A living computational model of each patient evolves with every new data input, providing an always-updated representation of their clinical status and trajectory.

From multimodal data → to a living patient model → to real-time clinical decisions.



Comprehensive Database for Stroke Patients



At this stage, SCUBA has provided clinical expertise and access to a diverse patient population, ensuring that the project's artificial intelligence algorithms are trained and validated using real-world clinical data.

The number of stroke patients hospitalized in our clinic in 2022 and 2023, considering admission restrictions related to the COVID-19 pandemic and including only those who provided informed consent for research participation, was approximately 136.

136 Patients

Total consented participants from SCUBA, enrolled during 2022–2023 following COVID-19 hospitalization restrictions.

96 Patients

Within the first **6 months post-stroke** — representing the acute and subacute rehabilitation phase.

40 Patients

More than **6 months post-stroke** — capturing the chronic phase and longer-term recovery trajectories.

[illegible]

Detailed Patient Records

The database is structured to capture every critical dimension of a stroke patient's clinical journey from initial presentation through discharge and beyond — including patient demographics, medical history, diagnosis, and treatment modalities — to support both clinical research and real-world decision-making.

1

Anamnesis & Medical History

Comprehensive past medical conditions, comorbidities, and individual risk factors are recorded for each patient. This context is essential for understanding how personal health history shapes stroke course and treatment response.

2

Demographics, Etiology & Symptoms

Essential information including age, gender, and education level is captured alongside stroke etiology and the full symptom profile. This enables identification of disparities in care access and helps tailor treatment approaches.

3

Ongoing Symptoms & Treatment Response

Longitudinal symptom data allows clinicians to closely track each patient's response to treatment and make timely, evidence-based adjustments to the care plan throughout the rehabilitation period.

4

Discharge Summary & Complications

Detailed discharge summaries document the complete clinical course, including any complications encountered. This information is invaluable for continuity of care and for understanding the long-term outcomes of stroke interventions.

Evaluating Stroke Outcomes

Rigorous, standardized outcome measurement is central to the STRATIF-AI project.

The following internationally validated scales are used to quantify impairment, functional disability, and rehabilitation progress across all enrolled patients.

Modified Rankin Scale (mRS)

The Rankin Scale measures the **degree of disability and overall functional outcome** following stroke. It provides a globally recognized benchmark for assessing independence in daily life and the effectiveness of clinical interventions.

Barthel Index (BI)

The Barthel Index quantifies the patient's capacity for **activities of daily living (ADL)**, including feeding, mobility, hygiene, and continence. It is a cornerstone metric for rehabilitation progress monitoring.

Functional Ambulation Categories (FAC)

The FAC scale monitors patient progress in **orthostatism and ambulation** during rehabilitation, including the level of physical support required for stance and gait — a critical indicator of functional independence.

- SCUBA is one of the clinical centers involved in data collection for the project.
- At this site, multi-angle biomechanical recordings are performed (video captures of motor rehabilitation exercises), directly contributing to the development and validation of the Digital Twin and AI models.
- All collected data feeds directly into the STRATIF-AI platform, where it is used to continuously refine and update each patient's digital twin — enabling simulations that anticipate recovery milestones and guide clinical decisions.
- The clinical team performs also standardized neurological assessments, including a project-specific adapted 4-level version of the Fugl–Meyer scale.
- These data are processed using pose estimation and motion tracking algorithms, developed in collaboration with Linköping University, Tree Technology, and SIMAVI, generating a high-fidelity virtual biomechanical representation of the patient — the functional Digital Twin used for analysis, prediction, and clinical decision support.

Clinical Validation Framework

STRATIF-AI's efficacy and safety are being rigorously evaluated across a coordinated program of six clinical studies, covering the full stroke care continuum and multiple European sites (with the first study, focused on prevention, already underway)

6

Clinical Studies

A multi-site validation program covering prevention, acute care, rehabilitation, and secondary prevention phases.

1st

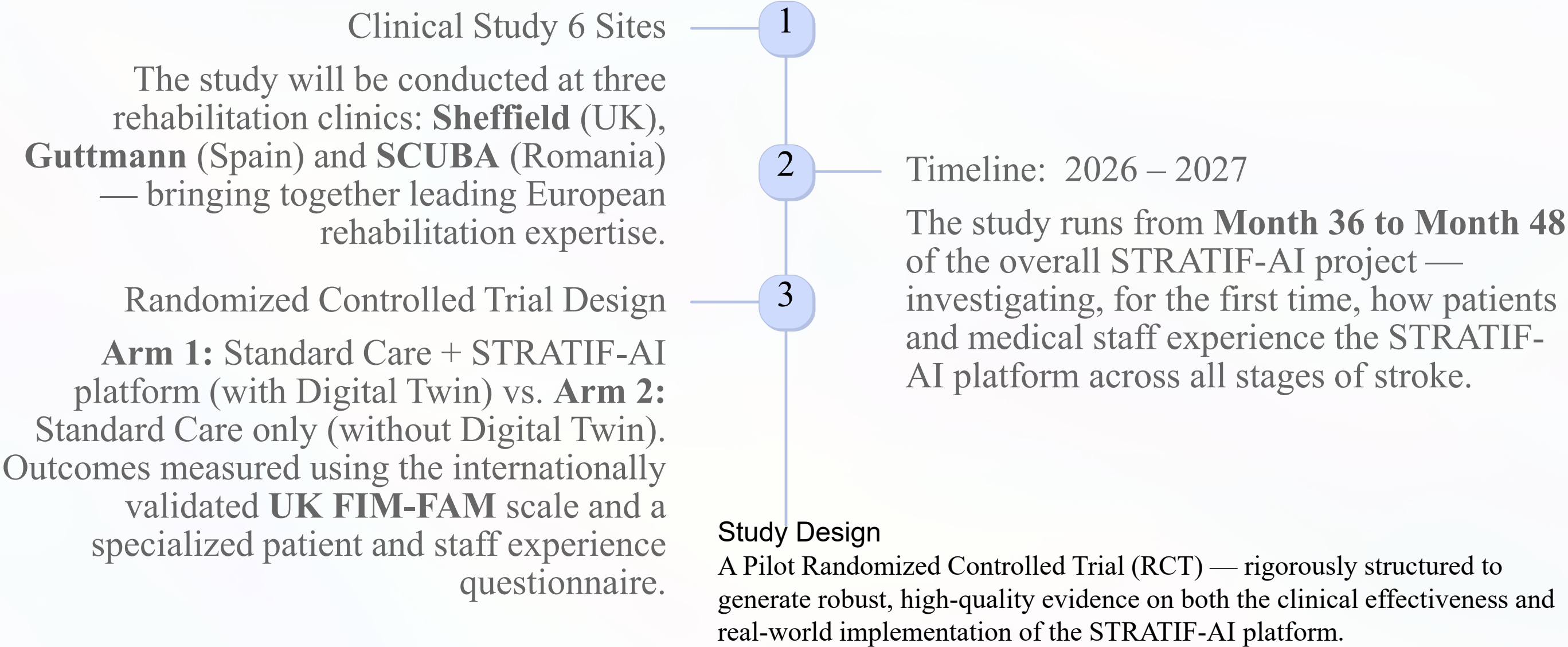
Real-World Implementation

We are moving beyond simulation and retrospective analysis into real-world clinical workflows across participating hospitals, building the evidence needed for large-scale adoption of STRATIF-AI in stroke care



Which Clinical Study Will We Participate In?

Of the six clinical studies to be conducted within the STRATIF-AI project, SCUBA's involvement is centered on **Clinical Study 6** — the final and most comprehensive study, which addresses the rehabilitation phase of stroke care across multiple international sites.



SCUBA's Role in Clinical Study 6

Location & Focus

This specific clinical study will be conducted at the **Neuromuscular Rehabilitation Clinic at SCUBA, Bucharest.**

It specifically addresses the **rehabilitation phase** of stroke — the period during which patients work to regain function and independence.

Study Period & Scope

For the first time in the context of the STRATIF-AI project, this study will systematically investigate how both **patients and medical staff** experience the usage of the STRATIF-AI platform across all stages of stroke care — capturing qualitative and quantitative implementation insights that will shape the platform's future development.



Study Objectives

Clinical Study 6 is designed with a clear hierarchy of objectives that build from immediate feasibility assessment toward long-term platform scalability and clinical adoption.

1 Primary Objective:
Feasibility &
Implementation

The primary aim is to assess the **feasibility of implementing the STRATIF-AI platform** in a real-world rehabilitation setting — evaluating usability, workflow integration, patient acceptance, and technical performance under clinical conditions at SCUBA.

2 Secondary Objective:
Platform Feedback &
Refinement

A structured secondary goal is to **collect detailed qualitative and quantitative feedback** from both patients and clinical staff — insights that will directly inform iterative improvements to the STRATIF-AI platform before wider deployment.

3 Strategic Goal:
Foundation for Scale

The pilot study is explicitly designed to lay the **evidence-based foundation** for future large-scale, multi-center clinical studies that can validate the STRATIF-AI platform for broad adoption across European stroke care systems.

Ethics Approvals Obtained

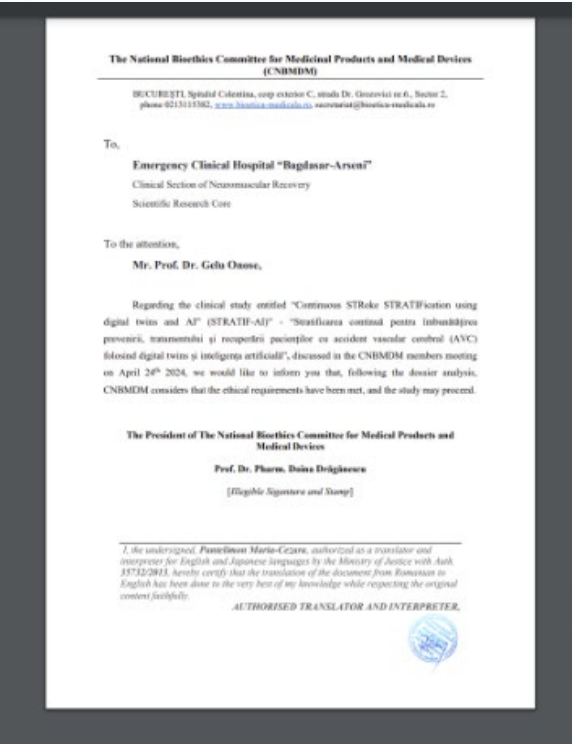
Regulatory and ethical authorization has been formally secured from both the local and national levels, enabling the full research protocol to proceed in compliance with all applicable standards for clinical research involving human participants.

Local Ethics Approval

The study methodology and application protocols have been reviewed and approved by the **Ethics Commission of SCUBA** (Spitalul Clinic de Urgență "Bagdasar-Arseni"), confirming compliance with institutional standards for patient safety and research integrity.

National Ethics Approval

Authorization has also been granted by the **National Bioethics Committee for Medical Products and Medical Devices**, validating the study design at the highest regulatory level in Romania.



The following official documents represent the formal ethics approvals that authorize the STRATIF-AI clinical study to proceed at SCUBA. These approvals were obtained following rigorous review of the study design, patient safety protocols, data management plans, and AI application methodology.

Study 6 — Randomized Controlled Trial Design

Study 6 is the rehabilitation component of the STRATIF-AI validation program — a pilot RCT designed to rigorously evaluate the Digital Twin's impact on post-acute stroke recovery in a real-world clinical setting.

Arm 2: Standard Care + Digital Twin

Arm 1: Standard Care

15 patients receive evidence-based standard rehabilitation protocols without Digital Twin augmentation. This arm establishes the comparator baseline.

15 patients receive the same standard rehabilitation enhanced by continuous Digital Twin monitoring enabling personalized and adaptive care . Participants in the intervention arm engage with the **STRATIF-AI Digital Twin** — an AI-capable avatar that interacts with the patient, visualizes their progress, and supports personalized goal-setting alongside standard rehabilitation therapy.

Total enrollment: N=30 patients. Study 6 represents the first prospective, controlled evaluation of the STRATIF-AI Digital Twin within an active rehabilitation program.

Study Participants

30

Total Patients

Enrolled across both study arms in this pilot RCT.

18–70

Age Range

Reflecting the broad demographic affected by stroke in clinical practice.

Eligibility Criteria

Participants are adults aged **18 to 70 years** presenting with a **first-ever ischemic or hemorrhagic stroke**, enrolled during the post-acute rehabilitation phase at SCUBA. The inclusion of both stroke subtypes ensures that findings will be broadly applicable across the most common clinical presentations.

Why These Criteria?

Focusing on first-stroke patients removes the confounding effects of prior cerebrovascular events, allowing the study to evaluate the STRATIF-AI platform's impact in a well-defined, clinically homogeneous cohort. The age range of 18–70 captures the primary working-age population most severely impacted by stroke-related disability — maximizing the societal relevance of the study's outcomes.

Inclusion & Exclusion Criteria

✓ Inclusion Criteria

- Post-stroke onset of ≥ 2 weeks at enrollment, ensuring the patient is in the post-acute phase
- Currently **admitted for inpatient rehabilitation** at the SCUBA Neuromuscular Recovery Clinic
- First documented stroke (ischemic or hemorrhagic), aged 18–70
- Ability to provide informed consent, with or without a legal representative

✗ Exclusion Criteria

- **Pre-existing major neurological conditions** — e.g., Parkinson's disease, epilepsy, dementia — that may confound outcomes
- **Severe pre-existing physical disability** unrelated to the index stroke that would impair participation
- Inability to tolerate the intervention protocol or provide valid informed consent



ETHICAL CONSIDERATIONS AND DATA PROCESSING

All participants will be informed at the beginning of the study of their characteristics, objectives and implications of their participation, in order to obtain their consent to participate.

For this, they will be provided with an informative document describing the type of the study

Patient Informed Consent Form Physician/ Principal Investigator: NEUROMUSCULAR REHABILITATION CLINIC, SCUBA Before giving your consent to participate in the focus group, please read the information sheet and check each box below if you agree. If you have any questions before signing the consent form, please discuss them with the principal investigator. You will receive a signed copy of this subject information sheet and the informed consent form for your records. Check the initial box after each statement: I Confirm that I have received information about the study mentioned above and have had the opportunity to read the information. I Confirm that I have had the opportunity to ask questions and have them answered. I Understand that my personal data will be collected, stored, and processed as part of the study. Processed personal data will include my name (first and last name), gender, and health data (as described in the information sheet). I Understand that the purpose of this study is to test the feasibility of the STRATIF-AI platform in collecting clinical data for scientific research purposes. I Understand that the information from the study will be combined with responses from other participants, anonymized, and may be published. Anonymized data will be stored for 15 years. I Understand that, as part of the open research network, the STRATI-AI application may evaluate my health records stored for the purpose of identifying candidates to participate in research. I Understand that I can withdraw my participation at any time. I Understand that my personal data will be deleted as soon as the purposes of processing have been achieved and if no other legal retention period opposes. I Understand that my personal data may be transferred to countries outside Romania but within the EU. I Understand that I am not obligated to participate in this study and may withdraw at any time without giving reasons. I Understand that withdrawing from the study will not affect my future treatment and care. I Understand that I can informally withdraw my consent for the processing of personal data at any time, with effect for the future, without negative consequences for me. I can send the withdrawal notification to: dpo@bagdasar-arseni.ro I acknowledge that a clinical project/study focusing on the beneficial effects of the STRATIF-AI platform/application on the prevention, acute treatment, and rehabilitation of patients with stroke (AVC) will be conducted within the Neuro-muscular Recovery Clinical Section of SCUBA. As both my attending physician and the project manager have thoroughly explained to me the details of this scientific research project and the fact that the use, application, and monitoring of this application do not have known significant adverse reactions or side effects. Additionally, all reasonable measures will be taken in accordance with current regulations to protect both my health and the confidentiality of my identity and medical data.	I agree to benefit from this experience by giving my consent to be included as a volunteer in this study. Signatures Patient Full name: Signature Date of completion: Authorized legal representative, if applicable Full name: Signature Date of completion: Person obtaining informed consent Full name: Signature Date of completion: Witness Full Name:..... Signature Date of completion: As a patient/person who has obtained consent/legally authorized representative, if applicable/participant in the study, I have received a signed copy of the informed consent. Full Name:..... Signature: Date of completion:
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Patient Informed Consent Form

Neuromuscular Rehabilitation Clinic, SCUBA — STRATIF-AI Clinical Study 6

Before providing consent, participants are asked to read the full information sheet and initial each statement below. A signed copy is provided to the patient for their personal records.

Information & Questions

I confirm I have received and read study information, and had the opportunity to ask and have questions answered.

Data & Privacy

I understand my personal data (name, gender, health data) will be collected, stored, processed under GDPR, anonymized, and may be published. Stored for 15 years.

Purpose of Study

I understand this study tests the feasibility of the STRATIF-AI platform for collecting clinical data

Voluntary Participation

I understand participation is **voluntary** and I may withdraw at any time without affecting my future treatment. Data deletion will follow upon request to dpo@bagdasar-arseni.ro.

Signatures are required from: **Patient** · Authorized Legal Representative (if applicable) · Person Obtaining Consent · Witness — each with full name, signature, and date of completion.

Intervention Protocol

Group 1: Standard Care + Digital Twin

Patients allocated to this arm will receive conventional post-stroke rehabilitation, similar to the control group; however, their therapy will be supported by the STRATIF-AI platform, which integrates Digital Twin (DT) technology to enhance and personalize the rehabilitation process.

How is DT technology introduced to patients and medical staff?

For patients: At the beginning of the study, patients will receive an explanation of the “digital twin” concept—a virtual model that tracks their progress, provides personalized feedback, and supports therapy adjustments.

For medical staff: The multidisciplinary team (physicians, physiotherapists, speech therapists, and occupational therapists) will participate in training sessions to understand how to integrate DT into therapy, interpret the generated data, and personalize interventions.



Group 2: Standard Care Only

The control group receives the full standard inpatient rehabilitation program at SCUBA without any Digital Twin interaction, serving as a **direct comparator** for feasibility and outcome metrics.

Intervention Protocol

Group 1: Standard Care + Digital Twin

What is the platform setup process?

Initial patient assessment: A functional and biomechanical evaluation is performed to establish a baseline. This includes motor, cognitive, and speech/language assessments.

Digital Twin generation: Based on the collected data, a personalized digital model is created and continuously updated using sensors, motion-tracking devices, and clinical feedback.

Integration with therapy sessions: The platform connects with rehabilitation devices (e.g., wearable sensors) to provide real-time data.



Initial Assessment

Questionnaires are used to evaluate the level of impairment and the patient's specific needs. To assess motor function in a patient who has suffered a stroke, detailed questions and tests may include the following:

Motor Assessment

Muscle Strength

Can you raise each arm above your head? (scored for each arm)

Can you lift each leg off the ground while sitting? (scored for each leg)

Coordination and Balance

Can you touch your nose with your index finger? (with eyes open and closed)

Can you stand up independently? Can you maintain balance on one leg for 10 seconds?

Manual Dexterity

Can you button your shirt or pick up small objects, such as coins?

Can you write a short sentence? (writing test)

Gait and Mobility

Can you stand up from a chair without assistance?

Can you walk 10 meters without assistance? (assessment of gait and step rhythm)

Muscle Tone and Reflexes

Do you experience spasticity, rigidity, or muscle spasms in your arms or legs?

Functional Assessment

Activities of Daily Living (ADL)

Can you dress yourself?

Can you brush your teeth independently?

Can you cook and eat independently?

Instrumental Activities of Daily Living (IADL)

Can you go shopping independently?

Can you use a phone or computer to communicate?

How does the DT function during therapy sessions?

The DT analyzes movement patterns, identifies compensatory strategies, and suggests personalized corrective exercises.

From Assessment to Personalized Intervention

Individualized Plans / Exercise Module

Quick access to a tailored list of exercises, with the ability to track completion.

- **Personalized Physical Therapy Programs**

Exercises and activities adapted to each patient's specific needs:

- **Video guidance for each exercise**

Demonstrations to ensure correct execution and proper technique

- **Real-time feedback**

Immediate correction of errors during exercise performance

How is the patient supported in using the DT?

During therapy: Clinicians assist patients in interpreting DT feedback, adjusting exercises, and setting realistic goals.

Outside therapy sessions: Patients are trained to use the platform independently, receiving personalized notifications and reminders for recommended exercises.

Technical support: A support team (therapists and/or IT specialists) ensures effective use of the system by both patients and staff.

The frequency of DT use varies depending on individual patient needs, ensuring an adaptive and personalized approach.

Data Collection Strategy

A **multi-modal data collection approach** ensures both objective clinical measurements and subjective patient experience data are captured comprehensively throughout the study period.



Clinical Assessments

Structured clinical evaluations conducted by trained rehabilitation staff at defined timepoints, capturing neurological and functional status changes over the inpatient stay.



UK FIM+FAM Functional Scales

The **Functional Independence Measure + Functional Assessment Measure** (UK FIM+FAM) is used as the primary validated functional outcome instrument, rated on a standardized 7-level scale.



Wearable Biometrics

Smartwatches worn by patients continuously monitor **heart rate (HR)**, blood oxygen saturation (**SpO₂**), and **sleep patterns**, providing real-time physiological data to enrich the dataset.

Self-care	1. Eating
	2. *Swallowing
	3. Grooming
	4. Bath/Shower
	5. Dressing Upper Body
	6. Dressing Lower Body
	7. Toileting
Bowel and Bladder	8. Bladder Management
	9. Bowel Management
Mobility	10. Transfers: Bed/Chair/Wheelchair
	11. Transfers: Toilet
	12. Transfers: Tub/Shower
	13. *Transfers: Car
	14. Locomotion: Walking/wheelchair
	15. Locomotion: Stairs
	16. *Community Mobility
Communication	17. Comprehension
	18. Expression
	19. *Reading
	20. *Writing
	21. *Speech Intelligibility
Psychosocial	22. Social Interaction
	23. *Emotional Status
	24. *Adjustment to Limitation
	25. *Use of Leisure Time
Cognition	26. Problem Solving
	27. Memory
	28. *Orientation
	29. *Concentration
	30. *Safety Awareness
	Calculating Sub Scale Scores
Impairment set	Neurological Impairment Categories

EXTENDED ADL	Introduction to Extended ADL
	Meal Preparation
	Laundry
	Housework
	Shopping
	Home Finances
	Work/ education

* FAM items

The UK FIM+FAM Assessment Tool

About the Instrument

The **UK FIM+FAM** (Functional Independence Measure + Functional Assessment Measure) was developed by the UK FIM+FAM Users Group (Version 2.2) and updated to align with the Australasian Rehabilitation Outcomes Centre training manual.

The UK FIM+FAM shall be used as a **unified assessment instrument** across all STRATIF-AI consortium sites participating in Clinical Study 6.

FAM items are rated on the **same 7-level scale as FIM items**, although the scaling structure is adapted to accommodate the more abstract nature of FAM domains — including cognition, communication, and psychosocial functioning.

<https://www.kcl.ac.uk/nmpc/assets/rehab/fimfam-manual.pdf>;
<https://www.kcl.ac.uk/nmpc/assets/rehab/part-1-fimfam-training-general.pdf>





Assessment Timeline

All enrolled patients are evaluated at four pre-specified time points, capturing both in-hospital recovery dynamics and longer-term functional outcomes following discharge.

- 1 — Admission
Baseline clinical, functional, and imaging assessments. Digital Twin initialized with patient data. Randomization to study arm.
- 2 — Discharge
End-of-inpatient-rehabilitation assessments capturing acute-phase recovery gains and readiness for community reintegration.
- 3 — 3 Months
Mid-term follow-up assessing sustained functional improvement, Digital Twin engagement, and patient-reported experience.
- 4 — 6 Months
Primary endpoint assessment capturing long-term functional recovery, quality of life, and secondary prevention outcomes.

In addition to clinical and functional data, we also evaluate patient experience.

A dedicated questionnaire captures both the patient's interaction with the Digital Twin and the performance of the underlying system



Patient Experience & System Evaluation

- **Specialized questionnaire** assessing two key aspects:

- ◆ **Patient Perspective**

- Impact of interacting with the **AI-driven Digital Twin avatar**

- Engagement, usability, and perceived benefit

- ◆ **System Performance**

- Functionality of the **hardware and software platform**

- Reliability and usability within clinical studies

As well as a specialized questionnaire targeting 2 aspects: - the impact on the patients in the study group of interacting with the AI-capable avatar – "Digital Twin" – and - the functioning of the hardware and software system used within the Clinical Studies).

Technology & Data Infrastructure

Data integrity, security, and regulatory compliance are foundational to the STRATIF-AI Study 6 data management framework.

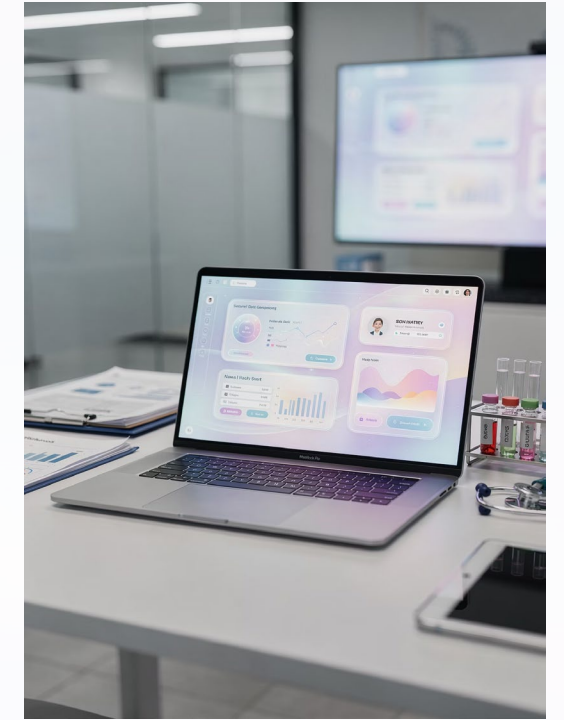
Secure & Encrypted Storage
All data is stored on **encrypted servers** with role-based access controls, ensuring only authorized research personnel can access identifiable or sensitive patient information.

Full GDPR Compliance

The study adheres to all requirements of the **EU General Data Protection Regulation (GDPR)**. Data may be transferred within the EU. Personal data is deleted upon completion of processing purposes.

All data is collected and managed via REDCap — a secure, validated, web-based research platform accessible from any internet-connected device, enabling convenient survey completion and centralized data management

REDCap Platform



Study Outcomes

Study 6 evaluates outcomes across **three** complementary domains — ensuring that STRATIF-AI is assessed not only on **clinical effectiveness**, but also on real-world **usability** and **patient experience**.



Feasibility

Can the Digital Twin be successfully integrated into a real-world rehabilitation workflow? Key metrics include data completeness, protocol adherence, and system uptime across the full study duration.



User Experience

How do patients and clinicians perceive and interact with the STRATIF-AI platform? Assessed through validated usability questionnaires, qualitative interviews, and engagement metrics.



Functional outcomes

Does Digital Twin-guided rehabilitation produce measurable improvements? Assessed using standardized motor, cognitive, and activities of daily living (ADL) scales across all four time points.

Motivational Modelling: Engaging Patients Through Digital Twins

From Passive to Active Care

In conventional rehabilitation, communication of treatment plans is predominantly **unidirectional**, limiting patient understanding of long-term goals and negatively impacting motivation.

Problem (conventional rehab):

- One-way communication
- Poor understanding of goals
- Low patient motivation

The STRATIF-AI digital twin framework enables **simulation of rehabilitation trajectories** — for example, predicted mobility at 6 months — visually communicated to patients in understandable, personalized representations.

STRATIF-AI solution:

- Visualizes recovery (e.g., 6-month outcomes)
- Explains progress in a simple, personalized way
- Actively engages the patient

Continuous Supervision (clinic and home)

The platform will support real-time adaptive feedback across **clinic and home environments**:

- Continuous movement monitoring
Detects incorrect exercise
- Provides automatic corrective feedback
- Updates recovery predictions in real time

This bidirectional loop between home and clinic is a concrete implementation of continuous stratification in daily practice.

Expected Impact

By placing a continuously updated Digital Twin at the center of the rehabilitation experience, STRATIF-AI is expected to drive meaningful improvements across three interconnected dimensions of patient and clinical outcomes.

↑ Patient Motivation

When patients can see their own data, track progress visually, and receive personalized feedback, intrinsic motivation to engage with rehabilitation is significantly enhanced — a key predictor of recovery success.

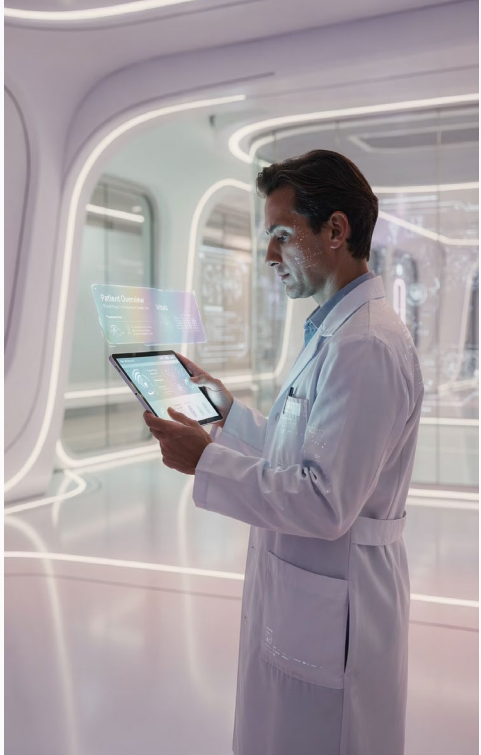
↑ Engagement

Continuous monitoring and real-time interaction keep patients actively involved in their care between formal therapy sessions, reducing the passive gaps that typically characterize inpatient rehabilitation.

❑ In other words, they will use the app to better understand their medical situation, and to set personal goals (just as they do in such conversations otherwise).

↑ Clinical Outcomes

Greater motivation and engagement, combined with more personalized, data-driven clinical decisions, are expected to translate into measurably improved functional recovery across motor, cognitive, and quality-of-life domains.



Impact on Clinicians

STRATIF-AI supports clinicians with better, faster, and more personalized decisions.

Decision Support

AI-driven analytics synthesize complex clinical data — including neuroimaging, physiological markers, and functional assessments — to guide evidence-based treatment decisions in real time.

Better Personalization

- Adapts treatment to each patient
- Adjusts as the patient progresses

Improved Communication

- Creates a shared understanding with patients
- Improves goal-setting and discussions

Conclusions

- ❑ So, the app for post-stroke patients could provide personalized rehabilitation exercises, track progress, offer reminder.
- ❑ Patients will also be offered to bring the app home, to use it during rehabilitation exercises, and in general to see how the twin is updated as they collect new data on themselves.

How is the patient configured for independent use outside therapy sessions?

Remote monitoring: Patients are provided access to a mobile or tablet interface where they can track progress, receive exercise recommendations, and report symptoms or difficulties.

- ❑ Patients can submit questions concerning the rehabilitation process, their clinical data, and the activities they have completed.
- ❑ These modules enable the medical team to view, respond to, and assist remotely with the management of the rehabilitation process.
- ❑ Also serves as a platform for providing ongoing support and resources to stroke patients and their families and improve their overall quality of life.

Conclusion and future impact

Study 6 — the SCUBA trial — represents the **first real-world clinical validation** of the STRATIF-AI Digital Twin in post-acute stroke rehabilitation.

It marks a pivotal step from theoretical concept to tangible clinical implementation, generating the evidence base required to scale this approach across health systems.

More broadly, STRATIF-AI has the potential to **redefine how stroke care is delivered** — transforming it from an episodic, reactive model into a continuous, personalized, and predictive system that follows the patient every step of the way

The STRATIF-AI platform presents a promising advancement in rehabilitation by integrating AI and DT technology to create personalized, engaging, and effective treatment experiences. By fostering motivation, improving adherence, and enhancing communication between patients and healthcare providers, this approach has the potential to revolutionize stroke rehabilitation.

A dedicated digital platform can deliver personalized exercise programmes, monitor progress, send reminders, and support telerehabilitation — improving functional independence and reducing long-term care costs



References

- Mulder ST, Omidvari AH, Rueten-Budde AJ, Huang PH, Kim KH, Bais B, Rousian M, Hai R, Akgun C, van Lennep JR, Willemsen S, Rijnbeek PR, Tax DM, Reinders M, Boersma E, Rizopoulos D, Visch V, Steegers-Theunissen R. Dynamic Digital Twin: Diagnosis, Treatment, Prediction, and Prevention of Disease During the Life Course. J Med Internet Res. 2022 Sep 14;24(9):e35675. doi: 10.2196/35675. PMID: 36103220; PMCID: PMC9520391.
- Thomas Platz. Clinical Pathways in Stroke Rehabilitation. Evidence-based Clinical Practice Recommendations.. 2021. ISBN 978-3-030-58504-4 ISBN 978-3-030-58505-1 (eBook). <https://doi.org/10.1007/978-3-030-58505-1>
- DeLisa's Physical Medicine And Rehabilitation Principles And Practice. SIXTH EDITION. EDITOR-IN-CHIEF Walter R. Frontera. Joel A. DeLisa. LCCN 2019003514 | ISBN 9781496374967
- Pranav Rajpurkar and Matthew P. Lungren, M.D., M.P.H. The Current and Future State of AI Interpretation of Medical Images. N Engl J Med 2023;388(21):1981-1990; DOI: 10.1056/NEJMra2301725;
- Barnes M, Kocer S, Murie Fernandez M, Balcaitiene J, Fheodoroff K. An international survey of patients living with spasticity. Disabil Rehabil. 2017 Jul;39(14):1428-1434. doi: 10.1080/09638288.2016.1198432. Epub 2016 Jul 6. PMID: 27385274.
- Watson T. Electrotherapy on the web. <http://www.electrotherapy.org/modality/transcutaneous-electrical-nerve-stimulation-tens>)
- https://www.bioness.com/Healthcare_Professionals/Exoskeletal_Products/H200_for_Hand_Paralysis.php
- Ring H, Rosenthal N. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. J Rehabil Med. 37(1):32-6, 2005
- https://www.bioness.com/Products/H200_for_Hand_Paralysis.php
- Ferris DP, Sawicki GS, Domingo A. Powered lower limb orthoses for gait rehabilitation. Top Spinal Cord Inj Rehabil. 2005;11(2):34-49. doi: 10.1310/6g14-um7x-519h-9jyd. PMID: 16568153; PMCID: PMC1414628.
- <https://www.kcl.ac.uk/nmpc/assets/rehab/fimfam-manual.pdf>;
- <https://www.kcl.ac.uk/nmpc/assets/rehab/part-1-fimfam-training-general.pdf>



THANK YOU!

