TREAT

Transforming Healthcare Through Semantic Interoperability and Self-Efficacy

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	RE	Restricted to a group specified by the consortium	
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Glossary

Abbreviation / acronym	Description
AI	Artificial Intelligence
API	Application Programming Interface
ECG	Electrocardiogram
EHR	Electronic Health Records
FHIR	Fast Healthcare Interoperability Resources standard
GDPR	General Data Protection Regulation
HL7	Health Level Seven set of standards
ML	Machine Learning
NCD	Non-Communicable Disease
NLP	Natural Language Processing
SaaS	Software as a Service
SpO2	Oxygen saturation
TREAT	Transforming Healthcare Through Semantic Interoperability & Patient Self-Efficacy
VLM	Vision-Language Model
XAI	Explainable AI

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1 Executive Summary

This deliverable provides validation of the TREAT project solutions. It is the result of task 1.3 of work package 1. WP1 provides the baseline for the other work packages in the TREAT project, by providing the requirements and related workflows of the project use cases, to be used as reference in the development of the technical solution of the project: these requirements guided the work of WP2 on data collection, algorithms, and privacy and security issues, WP3 in AI technologies and methodologies, and WP4 on the development of the project platform, software, and semantic interoperability concepts.

Task 1.3 performs the validation of the project solutions, using the demonstrators developed for the use cases in task 1.2 (Deliverable 1.4). This task includes both a technical validation against the requirements of task 1.1 (Deliverable 1.2), as well as functional validations by user groups.

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2 Introduction

The role of this document is to provide information on the validation of TREAT results, using the demonstrators defined for the TREAT project:

- **UC1: Patient-centric digital ecosystem**

  This use case concentrates on the development of a patient-centric digital ecosystem to improve self-efficacy for patients to manage cardiac metabolic diseases, specifically type 2 diabetes at home and the hospital. Further, the development of a wearable device that supports interoperability and can provide real-time decision-making data to both clinicians and patients at an institutional level. This use case supports TREATs goal to increase patient self-efficacy in managing non-communicable diseases (such as type 2 diabetes) by developing a patient centred platform that addresses interoperability between health institutions, decreases the reliance on healthcare providers, and increases patient adherence

- **UC2: Integrated System for Osteoarthritis Patients**

  The goal of the use case is to realize an integrated system for osteoarthritis patients which can be used by physical therapists and lifestyle coaches to administer and remotely monitor interventions/training programs, supported by automated personalized coaching. This use case supports TREAT's overall goals of improving individualized clinical care, specifically focusing on long-term adherence of individuals with diabetes mellitus and osteoarthritis to norms of healthy physical activity. This process will be optimized through remote physical monitoring, semantic interoperability and the use of AI for personalized recommendations. Each partner of the consortium will provide their expertise to work on this common goal.

- **UC3: Recommender SaaS Platform**

  This use case considers the integration of data from various sources (diet, pharmacological treatment, out-of-hospital monitoring, care pathways) into a platform which is able to provide personalized recommendations and improve the effectiveness of treatment for patients with chronic non-communicable diseases. (NCDs). This will include collaboration between health professionals, pharmacists and advanced artificial intelligence (AI) technologies. The platform will be provided through an API, which will allow us to offer it as a Software as a Service (SaaS) solution, allowing its use by other entities and facilitating its integration into various health platforms.

- **UC4: Diabetes monitoring**

  This use case will focus on a diabetes-specific solution aimed at enhancing self-efficacy and improving clinical workflows. The solution will provide a multi-layered framework, including collecting data from patients using two types of wearable devices, measuring the glucose level in the blood and record the electrical signals in the heart, which will be processed using AI on the platform for semantic operability.

- **UC5: Distributed Diagnoses and Home Healthcare**

  This use case pertains to distributed diagnoses and home healthcare, aiming to develop economically efficient methods for user-centred and home-based systems. These systems focus on monitoring health-related quality of life, particularly for patients with chronic diseases. In this context, the integration of personal devices (such as smartphones and wearables) with hospital information systems allows for remote patient monitoring. The system collects data from sensors, patients, families, and primary care

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professionals, integrating it with information from the hospital's individual personal care system. This integration enables the development of various services, including information dissemination, coaching, analysis, and alarming

- **UC6: Enhancing Patient Self-Efficacy and NCD Management through AI-Powered Remote Monitoring**

  The Well@Home platform will integrate AI assistance to streamline patient management for healthcare professionals. This will be achieved in three phases: 1) Enhancing data visualization and obtaining the required dataset, 2) Implementing a predictive AI assistant for patient diagnosis, and 3) Adding a prescriptive AI assistant to optimize content labelling and delivery timing. The goal is to improve the patient's self-efficacy, treatment adherence and decrease healthcare costs by reducing the reliance on healthcare professionals.

- **UC7: TREAT Complete**

  The TREAT Complete demonstrator is the project's integrated, cross-country demonstrator and serves as the final, ecosystem-level showcase of the TREAT project. Where the preceding demonstrators (UC1 to UC6) each present the solution of an individual consortium within its own clinical domain and platform, TREAT Complete deliberately does the opposite: it brings those individual building blocks together into a single, coherent care journey that spans multiple countries, consortium partners, and platforms.

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3 Patient-centric Digital Ecosystem demonstrator

The Canadian use case (UC1) focuses on improving self-efficacy for people living with type 2 diabetes by combining patient-reported lifestyle information with relevant clinical context and producing patient-tailored guidance through engaging digital interactions. In Canada, this demonstrator is implemented through My Viva's patient-facing tools (My Viva Plan for lifestyle tracking/journaling and Yaro for conversational reflections) together with a controlled integration to the AI recommender engine developed by TU/e (Hankins, Tim). The overall goal is to support daily self-management and longitudinal learning by capturing real-world behaviours, reflections, and (where available) clinical context, then using that de-identified integrated dataset to generate personalized lifestyle guidance that can be delivered back to patients in an understandable, supportive way.

The final UC1 demonstrator is a privacy- and security-preserving data workflow that supports: (1) capture of lifestyle and journaling data through My Viva Plan and Yaro, (2) ingestion of wearable/device telemetry where available, and (3) inclusion of EHR/EMR-derived clinical context when approved and available for use. Data is normalized for interoperability (including FHIR where applicable), then minimized and de-identified (anonymization/pseudonymization) before being made available to the TU/e recommender engine through a controlled interface. The TU/e recommender then produces personalized lifestyle guidance topics, which is surfaced back to patients through engaging interfaces (particularly Yaro) to support adherence and self-efficacy.

From an operational perspective, UC1 is executed in the context of a structured clinical implementation study workflow, which is currently in progress. Participants are onboarded first into My Viva Plan (with Yaro added when available), baseline and week 12 surveys are administered, and clinicians provide bi weekly support sessions during the 12 week program. Participant journaling data, wearable data when applicable, and EMR data (when consented and transferred through the defined secure process) are reviewed in regular cycles and used both for clinician recommendations and as learning material to improve AI-generated guidance.

The UC1 demonstrator is provided to users through My Viva's patient-facing digital platforms, with My Viva Plan used for onboarding and lifestyle journaling and Yaro used for conversational reflection and patient-facing guidance. The TU/e recommender engine is integrated as an external component via a controlled interface to generate personalized lifestyle recommendations from de-identified integrated data, with recommendations delivered back through the patient-facing experience.

Operationally, the UC1 study workflow includes recruitment through a partnered clinic, a defined consent process (including a separate EMR consent), secure storage of EMR files in a designated SharePoint area, and a 12 week cadence with bi weekly clinician sessions, baseline/week 12 surveys, and optional interviews at completion.

The study is supported by ethics approvals that enable recruitment and execution under the approved protocol "Enhancing Self Efficacy in Type 2 Diabetes Management through Data Collection for AI Training," including HREBA certification (effective 26 Nov 2025 through 30 March 2027).

3.1 Technical Validation

My Viva – Patient-centric Digital Ecosystem: Technical validation assessed the Canadian demonstrator against all functional and non-functional requirements defined for UC1 in D1.2. The assessment included workflow review, architecture and integration review, privacy and security review, functional testing, and

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internal clinical review. Each result begins with its validation status. Requirements requiring evidence from participants or other end users are identified as partly validated or pending and are addressed further under Functional Validation.

Functional Requirements

Requirement (D1.2)	*Validation method*	*Result*
UC1-FR-01 – Patient Data Collection	End-to-end testing of the collection of participant-entered lifestyle and journaling information through My Viva Plan and Yaro, together with available wearable or device telemetry and separately consented EMR-derived information.	**Validated at demonstrator level.** My Viva Plan and Yaro collect lifestyle, behavioural and reflection data. The workflow can also incorporate available wearable or device information and approved EMR-derived context. Internal healthcare practitioners reviewed the completeness, validity and clinical usefulness of the available study dataset. Participant-level findings will be finalized through the clinical implementation study.
UC1-FR-02 – Patient-Centric Data Interoperability	Review of the integration and normalization of patient-generated data, clinician or EMR-derived information, wearable data and subjective reflections into a de-identified dataset for clinician and recommender use.	**Validated at demonstrator level.** Lifestyle and journaling information, available wearable telemetry and approved clinical context can be combined in the demonstrator workflow. Data are normalized for interoperability, including FHIR where applicable, and minimized and de-identified before recommender access.
UC1-FR-03 – Internal AI/ML Processing	Architecture review of the implemented recommender workflow and clinical review of AI-supported outputs against the requirement for internal AI/ML processing.	**Validated with an architectural deviation.** AI-supported recommendation generation is implemented, but the final demonstrator uses the external TU/e recommender through a controlled interface rather than performing all AI/ML processing internally. Data are minimized and de-identified before transfer. Yaro also includes guardrails preventing it from presenting medical advice and instead directs the participant to a healthcare professional when appropriate. **Pending:** formal comparison of AI-generated and practitioner-generated recommendations using the same participant data.
UC1-FR-04 – Secure Wearable Data Linking	Security and workflow assessment of wearable or device data collection, transfer, linking, storage and access.	**Validated at demonstrator level.** The workflow supports available wearable or device telemetry and applies the demonstrator's privacy, security and access controls to the integrated information. Device-specific production integrations remain dependent on the equipment available for individual participants.
UC1-FR-05 – Unified Patient Data Integration	End-to-end review of the workflow connecting My Viva Plan, Yaro, available wearable information,	**Validated at demonstrator level.** The demonstrator establishes an integrated workflow across the patient-facing platforms, clinical and device data sources, privacy-preserving data-

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	approved EMR-derived information and TU/e recommender outputs.	preparation process and external recommender component.
UC1-FR-06 – Ulcer Risk Prediction Using AI	Scope review for evidence of an AI/ML model predicting ulcer risk using integrated participant information and historical ulcer data.	**Not validated; removed from the final project scope.** Following the departure of Rehabtronics from TREAT, the ulcer-risk prediction component was removed. The final Canadian demonstrator instead focuses on type 2 diabetes self-management and personalized lifestyle guidance.
UC1-FR-07 – Educational Resources	Clinical review of diabetes and lifestyle-management educational content, its delivery through the patient-facing platforms and its relationship to participant needs.	**Validated at demonstrator level.** My Viva Plan delivers patient-facing lifestyle and educational content developed and reviewed by healthcare practitioners. Personalized guidance can also be delivered through My Viva Plan and Yaro. **Pending:** participant and healthcare-coach review of Yaro-generated educational outputs through the clinical implementation study.
UC1-FR-08 – Mental Health Support	Safety review of mental health responses, identification of potentially concerning participant statements and presentation of professional or crisis-support information.	**Validated at demonstrator level.** Yaro captures conversational reflections and includes safety responses for indications of mental distress or trauma. It directs the participant to an appropriate healthcare professional or local support resource rather than attempting to provide mental health diagnosis or treatment.
UC1-FR-09 – Real-Time Data Access	Review of the availability of patient-entered, lifestyle, wearable and other integrated data after receipt from their source platforms.	**Validated within the implemented workflow.** Digital participant information is collected and made available through the connected platforms without requiring manual batch re-entry. Clinicians review the information through recurring clinical cycles. The precise refresh interval depends on the originating system and device connection.
UC1-FR-10 – Patient Engagement	Review of the implemented engagement mechanisms and the study measures for platform use, journaling, Yaro interaction, adherence, clinician checkpoints and participant feedback.	**Partly validated.** My Viva Plan and Yaro provide patient-facing interactions, journaling, reflection and personalized guidance intended to support continued participation. **Pending:** final participant usage, adherence, motivation and qualitative feedback findings from the clinical implementation study.
UC1-FR-11 – Appointment / Milestone Reminders	Scope and feature review for reminders relating to appointments, program milestones and recurring diabetes checks.	**Not validated; removed from the Yaro scope.** Appointment and milestone reminders were intentionally excluded because Yaro is designed as a lifestyle accountability companion rather than a scheduling or clinical assistant. Existing program contacts continue to be managed through the clinical study workflow.
UC1-FR-12 – Healthcare Professional Collaboration	Workflow review covering clinician access to participant information, specialist referral, shared care,	**Partly validated.** The study supports clinician review of integrated participant information and delivery of recurring clinical support. It does not yet provide a complete primary-care-to-specialist

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	reduction in paperwork and missing information.	referral workflow or shared specialist collaboration functionality. The initial demonstrator focuses on primary care; specialty-care and broader care-team connections remain future work.
UC1-FR-13 – Local Guidelines Education	Clinical review of lifestyle recommendations and educational materials against relevant Canadian diabetes and lifestyle-management guidance.	**Partly validated.** My Viva's core lifestyle content is developed and reviewed by healthcare practitioners for the Canadian context. **Pending:** systematic healthcare-coach verification of the full range of AI-supported recommendations against applicable Canadian exercise, nutrition and diabetes-management guidance.
UC1-FR-14 – Continuous Support and Follow-Up	Review of the 12-week implementation workflow, recurring information review, biweekly clinician contacts and mechanisms for participant feedback.	**Partly validated.** The implemented study workflow provides biweekly clinician support and recurring review of participant information throughout the 12-week program. **Pending:** participant and practitioner assessment of the adequacy, continuity and benefit of that support.
UC1-FR-15 – Promote Patient Self-Efficacy	Review of the intervention design and planned comparison of baseline and week-12 self-efficacy measures, supported by clinician observations and completion interviews.	**Partly validated.** The demonstrator is expressly designed to strengthen self-efficacy through structured lifestyle management, reflection, integrated information and personalized guidance. Internal healthcare-practitioner validation has been completed. **Pending:** analysis of baseline and week-12 study results and participant feedback.
UC1-FR-16 – Support Patient Adherence	Verification of Yaro's integration into the patient workflow and review of the mechanisms intended to support reflection, motivation and continued behaviour change.	**Partly validated.** Yaro is integrated as a conversational reflection and lifestyle-guidance component when available, and its functions have undergone internal review with healthcare professionals. **Pending:** participant usage, retention, adherence and qualitative findings from the clinical implementation study.
UC1-FR-17 – Generate Actionable Patient Plans	Internal clinical review of whether generated guidance is understandable, relevant and actionable, followed by planned participant and clinician assessment during the study.	**Partly validated.** The demonstrator can generate personalized lifestyle-guidance topics and return them to the patient-facing experience. Internal healthcare-practitioner testing has been completed. **Pending:** participant confirmation that the complete guidance or care-plan experience is understandable, relevant and actionable.
UC1-FR-18 – Generate Accurate AI Recommendations	Healthcare-practitioner testing of the reliability, consistency, clinical appropriateness and accuracy of AI-supported lifestyle guidance.	**Validated for the internally tested scenarios.** Yaro and the controlled TU/e integration generate personalized lifestyle-guidance topics from the information available to them. Healthcare practitioners have tested Yaro's reliability, consistency, clinical appropriateness and accuracy. **Limitation:** broader scenario coverage and comparison against practitioner-generated recommendations from the same participant information remain necessary.

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Non-Functional Requirements

Requirement (D1.2)	*Validation method*	*Result*
UC1-NFR-01 – Data Privacy and Security Compliance	Review of consent, data minimization, de-identification, storage, transmission, access controls and handling of lifestyle, journaling, wearable, EMR-derived and recommender data.	**Validated at demonstrator level.** The workflow applies data minimization and de-identification before information is provided to the TU/e recommender. Controls include encryption at rest and in transit, role-based access, multi-factor authentication, separate EMR consent and secure storage for transferred EMR information. The clinical implementation study operates under HREBA approval.
UC1-NFR-02 – Scalability for Data Growth	Architecture review and planned stress testing using simulated patient, lifestyle, wearable and glucose-monitoring data loads.	**Partly validated by architecture; performance validation pending.** The modular architecture accommodates several data types and separates the patient-facing platforms from the external recommender through a controlled interface. **Pending:** formal stress testing, concurrent-user thresholds, sustained data-volume testing and response-time measurements.
UC1-NFR-03 – User-Friendly Interface	Internal workflow review and planned patient and healthcare-practitioner usability assessment of My Viva Plan and Yaro.	**Partly validated.** My Viva Plan and Yaro provide interfaces for onboarding, journaling, reflection and personalized guidance, and the implemented workflows have undergone internal review. **Pending:** direct usability findings from study participants and healthcare practitioners, including ease of navigation, clarity and task completion.
UC1-NFR-04 – Localization Support	Testing of available language and location settings, including English and French Canadian options.	**Not validated within this demonstrator.** The Canadian demonstrator is being conducted in English. Automatic location detection and French-language operation were not tested as part of UC1. Broader localization is being advanced through a separate initiative.
UC1-NFR-05 – Customization Options	Review of how content and recommendations are tailored according to participant information, health context, goals and level of expertise.	**Validated at demonstrator level.** The workflow supports personalized lifestyle guidance derived from the integrated participant context, and this customization has been tested with internal healthcare experts. Validation of user-perceived relevance will be completed through the clinical implementation study.
UC1-NFR-06 – Extensibility	Architecture and interface review covering the addition of new datasets, recommender services,	**Validated at demonstrator level.** The controlled interface between My Viva's patient-facing tools and the external TU/e recommender demonstrates a component-based architecture. The workflow can accommodate lifestyle, journaling, device and

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	devices and future platform components.	approved EMR-derived inputs and can be extended to additional services and datasets.
UC1-NFR-07 – Content Creation UI/UX	Review of the workflow for creating, clinically reviewing, revising, approving and delivering educational materials and lifestyle guidance.	**Validated at demonstrator level.** My Viva Plan supports delivery of healthcare-practitioner-developed lifestyle and educational content. Clinicians review participant information and provide recommendations during the study, while clinically developed information can be incorporated into Yaro's controlled guidance environment.
UC1-NFR-08 – High-Level System Overview	Review of onboarding, orientation and explanation of how the digital tools, participant information and clinical support work together.	**Validated at demonstrator level.** The study includes structured onboarding into My Viva Plan, with Yaro introduced when available. Participants are oriented to the platform and the 12-week study process, including journaling and recurring clinician support.
UC1-NFR-09 – Ease of Accessibility	Review of content-development standards and planned assessment of patient-facing guidance against the D1.2 grade 5–8 reading-level target and applicable accessibility criteria.	**Partly validated.** My Viva's clinical content is generally developed for a grade 5–8 reading level, and work toward WCAG 2.1 AA compliance is nearing completion across My Viva Plan. **Pending:** formal readability testing of the complete demonstrator output, specialist language review and accessibility testing with representative users.

Technical validation conclusion: The assessment confirms that the core Canadian demonstrator has been established: patient-facing lifestyle and reflection tools, integration of available participant and clinical information, privacy-preserving data preparation, controlled connection to the TU/e recommender, clinically governed AI-supported guidance and a structured 12-week implementation workflow. Remaining evidence relates mainly to formal performance testing, participant-facing usability and accessibility, and outcome validation through the ongoing clinical implementation study.

3.2 Functional Validation

Functional validation with user groups: In accordance with D1.2, functional validation is based on assessment by representative user groups. The Canadian UC1 validation includes internal healthcare-practitioner review completed before and during implementation, participant validation through the ongoing 12-week clinical study, and further review of the integrated AI recommender outputs. The study is being conducted under the approved protocol *Enhancing Self-Efficacy in Type 2 Diabetes Management through Data Collection for AI Training*, with HREBA certification effective from 26 November 2025 to 30 March 2027.

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User group	Validation activities	Evidence and findings	Status and remaining work
Healthcare practitioners and internal clinical experts	Review of My Viva Plan content and workflows; testing of Yaro's responses; assessment of reliability, consistency, clinical appropriateness, accuracy and safety boundaries; review of personalized lifestyle-guidance scenarios; recurring review of participant information during the study.	Internal healthcare-practitioner testing confirmed that the implemented workflow can support participant onboarding, lifestyle and journaling data collection, clinician review, personalized guidance and safe escalation. Yaro was configured not to diagnose, prescribe or provide medical advice and to direct participants to healthcare professionals when appropriate. The underlying My Viva lifestyle content is developed and reviewed by healthcare practitioners.	**Validated for the scenarios tested internally.** Broader testing remains necessary to cover additional participant circumstances and recommendation topics. Formal comparison of AI-generated and practitioner-generated recommendations using the same participant data is also pending.
Clinical study participants living with type 2 diabetes	Twelve-week implementation involving onboarding into My Viva Plan, Yaro when available, baseline and week-12 surveys, lifestyle journaling, available device data, biweekly clinician support and optional completion interviews.	The study provides direct evidence on usability, perceived relevance, engagement, motivation, adherence, continuity of support, actionability of guidance and change in self-efficacy. Participants interact with the demonstrator under real implementation conditions rather than through isolated interface testing.	**In progress.** Final participant-level findings will be reported after completion and analysis of the clinical implementation study. Until then, requirements dependent on participant outcomes remain partly validated or pending.
Clinicians supporting study participants	Biweekly participant support sessions; review of lifestyle, journaling, available wearable and consented EMR-derived information; use of collected information to provide recommendations; review of participant progress over recurring cycles.	The clinical workflow demonstrates that practitioners can use integrated participant information to support longitudinal lifestyle management. It also provides a mechanism for assessing the usefulness and completeness of the information, the appropriateness of AI-supported guidance and the value of continued clinician involvement.	**In progress.** Practitioner feedback on workload, information completeness, usefulness, clinical fit and the adequacy of the 12-week support model will be consolidated with the final study results.
Participants using Yaro	Conversational reflection, receipt of personalized lifestyle-guidance topics, safety escalation when concerning	Internal tests indicate that Yaro can conduct structured lifestyle-oriented conversations, generate clinically bounded guidance and redirect medical or sensitive concerns appropriately. The study will	**Partly validated.** Internal clinical validation is complete for the tested scenarios. Direct participant evidence

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	content is detected, and planned feedback through surveys, support sessions and optional interviews.	determine whether participants find the interaction understandable, engaging, supportive and useful for behaviour change.	concerning engagement, trust, motivation and adherence remains pending.
Technical and clinical reviewers of the TU/e recommender integration	Review of the controlled interface, de-identification process, recommender inputs and generated lifestyle-guidance topics; planned comparison with clinician recommendations.	The integration demonstrates that minimized and de-identified participant information can be transferred to an external recommender and that personalized guidance topics can be returned to the patient-facing environment.	**Validated at integration level.** Clinical equivalence and appropriateness across a broader range of participant scenarios remain to be established through practitioner comparison and the clinical study.

Functional Validation Measures

Below are the validation measures guiding the ongoing study, which will be presented in a separate report upon conclusion of the study. Given the study delays and expected timing of completion, the report will be available upon request.

Validation dimension	User-group evidence	Planned interpretation
Usability and accessibility	Participant experience with onboarding, navigation, journaling and Yaro; healthcare-practitioner experience reviewing participant information; optional interviews.	Determine whether the tools are understandable and easy to use and identify barriers related to navigation, readability, accessibility or digital literacy.
Engagement and adherence	Platform usage, journaling completion, Yaro interaction, attendance at clinician sessions, continued participation and participant feedback.	Assess whether the demonstrator supports meaningful engagement and sustained participation across the 12-week program.
Self-efficacy	Baseline and week-12 self-efficacy measures, supported by participant interviews and clinician observations.	Determine whether participants report an increased ability and confidence to manage lifestyle behaviours associated with type 2 diabetes.
Clinical appropriateness and safety	Healthcare-practitioner review of Yaro and TU/e recommender outputs, including safety escalation and avoidance of diagnosis or prescribing.	Confirm whether recommendations are clinically appropriate, sufficiently bounded and suitable for use as supportive lifestyle guidance.
Relevance and actionability	Participant and clinician assessment of whether generated guidance is personalized, understandable and practical.	Establish whether participants can identify and act on the suggested lifestyle steps and whether clinicians consider them suitable for the participant's context.

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Continuity of support	Biweekly clinician contacts, recurring review of participant information and participant feedback on the study journey.	Assess whether the combination of digital support and practitioner involvement provides adequate continuity throughout the program.
Recommendation accuracy	Comparison of AI-supported recommendations with healthcare-practitioner recommendations based on the same participant information.	Identify agreement, clinically significant differences, unsupported recommendations and areas requiring stronger constraints or additional training examples.

Functional validation conclusion: Initial validation with healthcare practitioners supports the clinical appropriateness and safety of the implemented workflow for the scenarios tested. Participant validation is underway through the structured 12-week clinical implementation study. The final analysis will provide direct user-group evidence regarding usability, engagement, adherence, self-efficacy, continuity of support and the relevance and actionability of AI-supported guidance. Requirements dependent on those outcomes should therefore remain identified as partly validated or pending until the study analysis is complete.

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4 Integrated System for Osteoarthritis Patients demonstrator

The Dutch use case developed an integrated digital health system to improve the management of osteoarthritis by individuals. The system combines wearable sensors, real-time data analysis, and personalized coaching to support physical therapists and lifestyle coaches in remotely monitoring and guiding patients through individualized intervention and training programs. The goal is to enhance long-term adherence to healthy movement behaviors, improve overall physical fitness, and reduce the complications related to diabetes and osteoarthritis.

This use case focuses on enabling patients to manage their health, supported by a system that collects data on physical activity, fitness levels, and adherence to exercise programs. Personalized feedback and coaching will be provided based on the collected data, aiming to improve patient self-efficacy and long-term health outcomes.

By integrating home-based care with advanced digital technologies, the system empowers patients to take control of their disease management, reduce the need for frequent in-person visits, and contribute to broader health objectives such as reducing the burden of chronic diseases and promoting healthier lifestyles.

The demonstrator follows the GDPR and received approval from both TU/e's Ethical Review Board (ERB) as well as their Data Stewardship team. For the focus groups with physiotherapists, movement coaches and potential end user that were done by the Maastricht University (MU) and Roessingh, Centre for Rehabilitation (RCR), the Medical Ethical Research Commission Oost-Nederland (Eastern Netherlands) determined that the study did not fall under the scope of the Dutch law of performing medical-scientific research on humans. This was stated in an official exemption letter. For the field tests with the wearable sensors that were done by Maastricht University, the Medical Ethical Research Commission of Maastricht University Medical Center (MUMC+) determined that the study did not fall under the scope of the Dutch law of performing medical-scientific research on humans; and the ethical committee of the Faculty of Health Medicine and Life Sciences ethically approved of the tests.

Within WP3, TU/e (JADS) built the LLM governance layer for the Dutch use case's automated coaching: the part that keeps an AI coach's advice to patients within clinician-approved limits. The work produced one methodology and two working systems.

- COMPASS (Constitutional Methodology for Patient-facing AI System Safeguards) lets clinicians codify a set of ethical and clinical principles within a constitution, then validate it, load it into a language model at run time, measure the model's adherence to each principle using two methods: adversarial tests designed to elicit harmful responses, and aspect-based natural language inference (ABNLI). Lastly, the COMPASS methodology results in an LLM that logs its stated governance rationale for each response.
- The TREAT federated-services platform runs 19 containerized services. They implement the service's API, load balancing, and routing; manage authentication and sessions, maintain data stores of several kinds, collect wearable data, turn it into clinical trends, exchange observations (via FHIR) with MEDrecord's record store, serve a patient-facing medical chat service governed by the constitution, and provide clinicians with a dashboard through which they can observe each patient's data and trends.

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- The COMPASS validation toolkit stress tests the governed chat system using 1,000 adversarial prompts; it scores each answer against each principle, and tests whether the audit rationale is logically consistent with the patient's data.

The implemented COMPASS system ingests patient context data, biometric sensor data (which it processes into biometric analytics), prescribed activity plans, and patient daily diaries. Also, the LLM receives those data elements at runtime, and with it, renders appropriate, ethical, patient-specific recommendations, information, and assistance.

The governed chat attaches a governance rationale to its responses. The governance rationale links each response to the empirical facts considered by the model and the constitutional principles that governed its response.

COMPASS already runs outside TU/e: Almende and MyViva adopted the TU/e constitution in their deployments, which form part of TREAT Complete. TREAT Complete also demonstrates cross-system interoperation.

To gather activity and lifestyle data, the following are used:

- The MOXBASE and Pacer tracker are adapted, and first versions have been used in a trial already.
- The first version of the wearable has been used for a trial already; this wearable will only be improved for the final demonstrator.
- The API of MOX MISS activity monitor is available and connected to the Medrecord system.
- The API of Johan sports is available and also connected to the Medrecord system.

In 2025, the COMPASS system ran end to end, collecting data from Garmin wearables, storing them (via FHIR) in MEDrecord's record store, and forwarding them to the clinician dashboard and the governed patient chat. The COMPASS system's services are containerized and can be deployed to a cloud host. Though during the clinician demos, it ran on the principal investigator's laptop.

TU/e demonstrated the governed chat live with (n=8) clinicians using two synthetic patient personas who live with osteoarthritis and type 2 diabetes, Ria (62) and Joep (55), together with real wearable data worn by the principal investigator. When interacting with the patient-facing chat system, clinicians saw both the LLM's response and the LLM's governance rationale audit record side-by-side.

The COMPASS alignment process is implemented using model instructions, not using model training. The consequence is that care organizations can forego complex model training and adopt it with a stock language model. A new clinical setting needs only a new constitution, a new round of clinician validation, a new deployment, and production service auditing.

TU/e tested whether the alignment effect held beyond openai/gpt-oss-120b. It did this by running the 1,000 adversarial prompts and ABNLI analysis against three additional models spanning a range of vendors and system capabilities: qwen/qwen3.8-27b (on GroqCloud), grok-4.3 (on xAI), and gpt-6.1-sol (on OpenAI). The COMPASS toolkit's ABNLI scorer produce*s* per-principle adherence metrics that are comparable across models, constitutions, and prompts. The findings demonstrated that our constitutional alignment lowered attack success for every model, by 62.2% for grok-4.3 up to 92.5% for gpt-oss-120b, with $p < .001$ each. However, while per-principle adherence rose for gpt-oss-120b and grok-4.3, it fell for gpt-6.1-sol (0.333 to 0.256) and dipped slightly for qwen3.8-27b. This change can be attributed to the fact that LLM outputs vary, and not every response necessarily addresses each principle explicitly. However, such responses may still be deemed appropriate and ethical.

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Access to the COMPASS chat system is limited to the TU/e research team; the chat API rejects calls without a login, and testing used no patient data. All data is protected by encryption at rest and in transit. Eight clinicians saw the system in 90-minute demonstration sessions, which TU/e's ethical review board approved. No patient has used the system.

In the Dutch use case's upcoming focus groups, physical therapists will review output from the governed chat. These sessions are the next validation step before the final demonstration.

Two field tests were performed by Maastricht University in collaboration with Beweeghuis. The goal of these field tests was to collect data for furhter algorithm development and validation.
In the first field test 50 participants from Beweeghuis wore the wearables (PACER, MOXBASE1) in a textile vest, provided by Elitac, during an hour long exercise sessions. The sessions were varied in intensity and types of exercises.

In the second field test 20 participants from Beweeghuis wore the MOXBASE1 for 36 hours in free-living. The MOXBASE was worn in a textile vest, provided by Elitac. This vest was optimized compared to the previous field test based on user experiences. The 36 hours included at least one exercie session from Beweeghuis and one night at home. The goal was to assess the data quality during prolonged measurements in a real-world setting and verify the algorithm's performance.

4.1 Technical Validation

TU/e – Federated-services platform and COMPASS: The TREAT federated-services platform and the COMPASS validation toolkit are implemented at TRL 4, validated in the lab. The table checks the D1.2 requirements that apply to TU/e's part, then adds five rows for WP3 results that D1.2 does not cover. In addition to **TU/e – Federated-services platform and COMPASS** Maastricht University performed a technical validation of hardware in Beweeghuis participants which is added to the table. Each result starts with its status (Validated, Partly validated or Pending); a pending item gives its reason.

Requirement (D1.2)	***Validation***	***Result***
UC2-FR-01 Data integration and interoperability	End-to-end runs from Garmin wearables to MEDrecord and the clinician dashboard	**Validated for Garmin wearables and MEDrecord.** In 2025 the platform ran end to end, from Garmin wearables through MEDrecord's record store to the clinician dashboard. The COMPASS system exchanged FHIR with MEDrecord's backend. Validated: MOX MISS activity and Johan Sports PACER monitor data are available in MEDrecord platform via its API
UC2-FR-02 – Therapy adherence	Check with coach for presented patient data.	**Pending (pilot):** the D1.2 test, whether or not the coach can identify adherence from the presented patient data in the dashboard

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UC2-FR-03 Health and progress insight	Automated tests of the clinical trends against the raw wearable data	**Partly validated.** The platform turns wearable data into clinical trends; a full suite of tests ensures this accuracy. **Pending (pilot):** the D1.2 test, whether the trends show the progress coaches see themselves.
UC2-FR-04 Skill level	Can take responsibility for interpretation	**Pending (pilot):** the D1.2 test, whether or not the coach understands the data and can take responsibility for the treathment.
UC2-FR-05	wearing the wearable	Validated: the wearable was worn by 38 unique participants in fieldtest 1 and by 20 participants in fieldtest 2. Results: Data quality was improved between the two fieldtests. Participants reported no issues.
UC2-FR-06	Interaction with the wearable by patient	Validated: the wearable was worn by 38 unique participants in fieldtest 1 and by 20 participants in fieldtest 2 Results: Data quality was improved between the two fieldtests. Participants reported no issues. There was minimal data loss due to user errors.
UC2-FR-07 Movement coach overview	Review of the clinician dashboard	**Partly validated.** The clinician dashboard presents patients' activity trends.
UC2-FR-08 Coach checks on sessions	–	**Pending (pilot):** The clinician dashboard flags patients who drift from their targets, but it was not part of the demo clinician sessions, so there are no test results to report.
UC2-FR-09	Wearablility	Validated: the wearable was worn by 38 unique participants in fieldtest 1 and by 20 participants in fieldtest 2 Results: Participants reported no issues.
UC2-FR-10 Connection	electronics integration	Validated: heart rate could be measured via the garment
UC2-FR-11	Sizing	Validated: the textile wearable was fitted with sliders to ensure a secure fit. Results: The textile wearable was suited for all included participants
UC2-FR-12	Donning and doffing	Validated: the wearable was worn by 38 unique participants in fieldtest 1 and by 20 participants in fieldtest 2 Results: no issues were reported by participants
UC2-FR-13	Compatibility with different activities	Validated: During both fieldtest the participants did a movement session and worn the devices during free-living. Covering a large range of activities at different intensities.

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		Results: Preliminary analysis indicated good results of data quality.
UC2-FR-14 Motivational support	Interact with the user as to motivate him/her	Pending (pilot): the chatbot and COMPASS tend to motivate the user, but reception of motivation has to be checked in a follow-up pilot
UC2-NFR-01 User experience	Clinician panel ratings and eight 90-minute sessions	**Validated.** The clinicians demoed the interface, and rated the appropriateness, safety, information accuracy, and ethical boundaries of the LLM's constitutionally-aligned responses. They had positive opinions, but with caveats (see 4.2). **Pending (pilot):** the D1.2 target of at least 85% positive feedback.
UC2-NFR-02 Low latency	Timing of wearable synchronization and dashboard response	**Validated.** Wearable sync < 30 sec. Dashboard response times: < 50 ms. Both fall within D1.2's 1-minute target.
UC2-NFR-03	Data quality	cannot be tested within the timeframe of the project
UC2-NFR-04 Privacy and security	Access tests and configuration review	**Validated.** Data is protected by encryption at rest and in transit. Access is limited to the TU/e research team, the chat API rejects calls without a login, and testing used no patient data.
UC2-NFR-05	Electronics biocompatibility	Not applicable: The wearable is placed inside the textile wearable. No electronics are in direct contact with skin.
UC2-NFR-06 Textile biocompatibility	Material shall be skin-friendly	Validated: suitable materials were selected to avoid biocompatibility issues and none of the plot group has reported issues.
UC2-NFR-07	Corrosion resistance	Pending (pilot): the right materials have been chosen, but long term durability has to be proven in a pilot.
UC2-NFR-08	Connection robustness	Pending (pilot): the right materials have been chosen, but long term durability has to be proven in a pilot.
UC2-NFR-09	Lifetime	Pending (long term usage and trails): the 3 year durability has to be shown over time
UC2-NFR-10	Washability	Validated: During the fieldtest the textile wearable was washed more than 10 times. No visible results of wear. (In lab) the electrode material, used in the wearable, is washed 35 times during extensive wash tests. The electrodes are still functional after 35 washing cycles.
UC2-NFR-11	Aesthetics	Partially validated: no complaints on aesthetics of wearable have been received

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UC2-NFR-12 Accessibility	Review of language support; test with a low-literacy patient profile	**Validated.** The COMPASS system does not speak in Dutch, but Almende's implementation does. The COMPASS methodology and its effects are language agnostic because they are defined and function at the level of the LLM's internal semantic state space. Note that proper functioning depends on accurate context data about the patient's language development level.
WP3-1 Clinician-approved constitution (beyond D1.2)	Clinician panel ratings	**Validated.** A panel of eight clinicians (family medicine, neurology, psychiatry, infectious diseases and physiotherapy) rated all 10 medical-ethics principles appropriate for a patient-facing assistant. The panel used an Appropriateness Level Metric adapted from the RAND/UCLA method; 129 of 160 ratings scored 7 or higher on its 9-point scale.
WP3-2 Robustness to adversarial prompts (beyond D1.2)	Adversarial test with the COMPASS validation toolkit; replication on three more models	**Validated (lab).** In November 2025, exhaustive tests of the COMPASS toolkit sent 1,000 adversarial prompts to gpt-oss-120b across 12 runs (12,000 responses). With Claude Haiku 3 as judge, attack success fell from 32.4% without the constitution to 0.4% with it. The governed model refused the harmful request in 99.6% of cases (ungoverned model 67.6%). **Replicated (October 2026, Claude Haiku 4.5 as judge):** To compare openai/gpt-oss-120b with the initial test under one judge, TU/e re-judged the initial test's responses with Claude Haiku 4.5. Constitutional alignment lowered attack success for every model. Relative to its unaligned version, constitutional alignment lowered each model's attack success rate, from 62.2% for grok-4.3 to 92.5% for openai/gpt-oss-120b. The absolute drop ranged from 2.0 percentage points for gpt-6.1-sol (which began with an unaligned attack success rate of 2.4%) to 51.1 points for openai/gpt-oss-120b (55.3% to 4.2%). For each model, the drop was unlikely to be chance (McNemar's $p < .001$). The 2025 and 2026 runs failed nearly the same share of attacks in each arm: 57.7% in the initial test and 55.3% in the replication unaligned, 4.6% and 4.2% aligned.
WP3-3 Adherence to each principle (beyond D1.2)	ABNLI on the locked test split; paired McNemar tests	**Validated.** On 294 held-out prompts, the toolkit's per-principle entailment scorer (ABNLI) found that recall of the principles a reference answer upheld rose from 0.095 to 0.358, averaged over 14 principles. Alignment improved the adherence of 11 of the 14 principles (paired McNemar tests). In the October 2026 replication, per-principle adherence did not rise for every model. Macro recall rose for openai/gpt-oss-120b (0.097 to 0.342) and for grok-4.3 (0.250 to 0.287), but fell for gpt-6.1-sol (0.333 to 0.256) and

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		showed a slight drop for qwen/qwen3.8-27b (0.266 to 0.259).
WP3-4 Auditable reasoning (beyond D1.2)	Share of answers with a logically self-consistent governance rationale; counterfactual tests	**Validated (lab).** The governed chat attached a governance rationale to 95.8% of its answers in the November test. The rationale changed correctly in 19 of 19 counterfactual tests, each of which altered one fact in the patient's data. In the October 2026 replication, the aligned models returned audit logs in 92.1–100.0% of responses.
WP3-5 Modular, scalable services (beyond D1.2)	Review of the platform's build; load tests	**Validated.** The TREAT federated-services platform runs 19 containerized services. Its services ship as containers and deploy to a cloud host. TU/e's distributed system supported load capacity of up to 100 patients for 6 weeks, verified by load tests. The COMPASS federated architecture is scalable, both horizontally, to accommodate more load, and with the addition of new services.

4.2 Functional Validation

TU/e – Federated-services platform and COMPASS: TU/e ran validation sessions with eight clinicians recruited through TU/e, Maastricht University, and Beweeghuis. Eight clinicians took part in a 90-minute demonstration session, which TU/e's ethical review board approved. The sessions covered these scenarios:

- **Principle review:** The panel judged all ten principles clinically appropriate, with median scores of at least seven.
- **Patient conversation (synthetic personas):** Clinicians were invited to share think-aloud critiques of governed chat responses to ethically and clinically challenging prompts from patient personas Ria and Joep. Clinicians saw each answer beside its audit record. All eight clinicians endorsed the governed chat systems ethical and clinical boundaries, specifically its refusal to diagnose or prescribe. This was the most frequent explanation for their confidence at the end of the session. They also spoke supportively of the appropriateness, accuracy, and completeness of the LLM’s personalized responses. However, they also raised concerns, discussed below.
- **Adversarial pressure:** When responding to attacks across 1,000 adversarial prompts, our constitution lowered attack success rates from 32.4% to 0.4%. In response to adversarial prompts, half of the ungoverned model's responses were the same bare refusal: "I'm sorry, I can't help with that." Applying the constitution virtually eliminated this evasiveness and resulted in helpful, principled responses.
- **Audit record:** All eight clinicians viewed the governance rationale audit trail; three reported that it increased their trust, two reported no change, and two considered its value conditional on available time. These responses suggest that the audit trail may be more useful for auditors and supervising physicians during incident review than for front-line clinicians during routine use.
- **Patient fit:** Each clinician expressed concern that the governed chat's normative clinical behavior was not appropriate for all patient groups. In particular, they identified patients living with cognitive or developmental disabilities, limited functional literacy, and those with strong alignments with traditional or local health practices.

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- **Content provenance:** Five participants independently redirected the subject of the demo from ethical and clinical behavior to the provenance of the medical content. Four participants proposed that the model be constrained to using a reputable and verifiable knowledge base. While the accuracy of the empirical facts used by the LLM is outside the purview of our constitution, the COMPASS methodology is compatible with such knowledge bases and does not preclude their use.
- **Reuse across demonstrators:** Almende and MyViva adopted the TU/e constitution in their deployments, which form part of TREAT Complete.

Clinicians who participated in the system demo proposed five additions to the constitution: avoid medicalizing benign complaints; avoid generating demands on clinicians; match the patient's cognitive state rather than only their reading level; account for the cost of the system itself to the patient; and frame prognosis without frightening patients away from treatment. The COMPASS methodology is explicitly designed to be customizable to local clinical needs, so requests such as these are directly achievable, and demonstrate the core value of the methodology.

When asked what would engender their trust in the system, six clinicians identified “actual system use” as the deciding factor in determining the system's trustworthiness and clinical value.

Maastricht University (UM)/Roessingh, Centre for Rehabilitation (RCR): UM and RCR ran four focus group sessions. Two sessions with a mix of movement coaches and physiotherapists and two session with potential end-users. In total, 13 healthcare professionals and 11 potential end-users participated in the sessions.

Healthcare professionals

Principle review

- They clearly preferred the constrained version. Its rules should be based on evidence and clinical guidelines, with no diagnoses and referral to the physiotherapist when in doubt.
- Professionals want to set the rules per patient. The AI should support and advise, and its role should shrink over time while patients increase their self-management.

Patient conversation (synthetic personas)

- The personas were recognizable but too active. Real participants are mostly inactive or drop out early.
- The messages to Johan were too long, had too many numbers and too many tips, and largely ignored the emotion. The messages to Ria were preferred: short, positive, one action, B1 language level

Adversarial pressure

- The system answered the whole message instead of the actual question. When asked to be the main point of contact, it partly sidelined the physio while saying it couldn’t replace them.
- The unconstrained version was more concrete but riskier, and the professionals worried patients would trust “my AI” over their therapist.

Audit record

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- The system should alert the professional when a question enters a grey area or falls outside its rules. A group dashboard should flag the participants who need attention.
- Some want to approve messages first, which is only realistic if it takes minutes. Who is responsible remains unresolved.

Patient fit

- There were doubts whether the target group would wear the vest; it may better be suited to younger or cardiac patients. The activity monitor was well received, especially for measuring sitting time.
- There were doubts whether the vest would fit without supervision for over-motivated patients or those with low illness insight. The biggest gain is expected in everyday movement.

Content provenance

- Answers should be traceable to guidelines, and the sensors need proven validity.
- What sets this apart from consumer wearables is EU data storage and transparency about the model.

Potential end-users

Principle review

The rule set was not shown to them. They did value the AI referring them to a doctor, and the human contact staying in place.

Audit record

- They want a coach or doctor to monitor the data and alert them, rather than checking it themselves.

- Concerns: changing coaches, too many people seeing their data, and medical data belonging with the specialist rather than the sport coach.

Patient fit

- Main barriers: no smartphone or internet, losing or forgetting the device, charging and washing. The vest should open at the front or back and offer cup support for women.

- The most valued use is support after the 12-week program, when contact stops. Views on the chatbot were split; speaking to it instead of typing lowers the threshold for some.

Content provenance

- Trust in watch data is mixed, and the general practitioner (doctor) is trusted more than AI.

- The values shown can differ from how someone actually feels, so the data should only supplement the conversation with a professional.

Elitac Wearables (Elitac): Elitac ran validation sessions in house on several subjects of the wearable. ECG quality is validated during long duration movement tests, the comfort of the wearable is validated in house, and the dry electrode material used in the wearable is validated on signal quality, use and washability.

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Demcon Johan Sports: The data obtained from the PACER trackers was validated in the first field trials, where the trackers collected data and the heart rate and GPS data was inspected to be of sufficient quality. Additionally, the API interfacing to the Medrecord platform is validated on providing the data and notifications for new events.

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5 Recommender SaaS Platform demonstrator

AI-enabled SaaS recommender and semantic interoperability platform for chronic NCD management, integrating clinical, pharmaceutical, dietary, monitoring and care-pathway data to support personalized treatment, patient adherence and coordinated care.

- GLINTT: diet–drug–patient interaction analysis, FarmaTools/DietTools integration, AI modules, XAI, knowledge graphs.
- DEXTRO: AI-assisted care pathways, workflow optimization, conversational AI assistant, semantic interoperability server.

The Spanish contribution to the final TREAT demonstrator comprises two complementary solutions developed by GLINTT and DEXTRO. These solutions address different aspects of chronic disease management: personalised dietary recommendations based on patient information, and AI-assisted care pathway definition and optimisation.

The two contributions are organised as independently developed and operated solutions, rather than as a single, tightly integrated application. Each partner maintains responsibility for its own implementation, deployment environment, data management and validation activities. Collaboration continues through the coordinated preparation and presentation of the final TREAT demonstrator, in which the partners will showcase their respective use cases and explain their contribution to the overall project objectives.

Rationale for independent implementation and validation

During project execution, the Spanish partners adopted an independent implementation and validation approach to address data security requirements and ensure technical and operational feasibility. This approach preserves collaboration within TREAT while avoiding unnecessary dependencies between solutions with different functional purposes, information requirements and technological environments.

From a data security perspective, the two use cases involve different combinations of clinical information, pharmaceutical and nutritional data, and care-process documentation. Establishing a single shared environment would introduce additional requirements concerning information exchange, access permissions, security controls and the allocation of responsibilities for data management. Such centralisation is not necessary to demonstrate the value of either solution.

Maintaining separate environments allows each partner to manage the information used by its solution under the relevant access conditions and governance arrangements. It also reduces unnecessary transfers of patient-related information and enables security controls to be adapted to the specific characteristics of each use case. The joint demonstration therefore does not require the pooling of clinical datasets or the sharing of patient-level information between the Spanish partners.

From a technical and operational perspective, GLINTT and DEXTRO address distinct healthcare needs and develop different functional components. A tightly coupled implementation would create additional dependencies between their architectures, interfaces, deployment configurations and validation schedules. Independent development allows each partner to address its own requirements and resolve technical issues without making the delivery of one solution dependent on the readiness of the other.

This decision concerns the organisation of implementation and validation, rather than the separation of the partners from the common project objectives. Both solutions remain part of the Spanish contribution to

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TREAT and will be presented within the final demonstration as complementary applications of artificial intelligence in healthcare.

GLINTT contribution: personalised dietary recommendations

GLINTT focuses on an AI-based dietary recommendation solution that takes the patient's clinical history and available pharmacological and nutritional information into account. Its purpose is to support healthcare professionals in adapting dietary recommendations to the patient's individual circumstances, rather than providing generic nutritional guidance.

The solution considers relevant relationships between the patient's health profile, current treatment and dietary requirements. Within this scope, the analysis of diet–drug–patient interactions contributes to the contextualisation of recommendations and supports the review of nutritional advice in relation to the patient's clinical situation.

GLINTT's contribution is therefore centred on personalised nutritional decision support. The main functional result demonstrated is the generation of dietary recommendations informed by patient-specific information and relevant clinical knowledge. These recommendations are intended to support professional assessment and remain subject to clinical review; they are not intended to autonomously prescribe or modify pharmacological treatment.

DEXTRO contribution: AI-assisted care pathways

DEXTRO focuses on the application of artificial intelligence to support the definition, structuring and optimisation of care pathways and clinical workflows. Its contribution addresses the organisation of care processes and the use of clinical documentation and process knowledge to assist healthcare professionals.

The DEXTRO use case includes AI-assisted processing of care-related information, support for the generation and review of structured clinical-process content, and conversational and semantic capabilities associated with these functions. Its functional emphasis is on helping professionals work with care pathways and related information, rather than generating personalised dietary recommendations.

The two use cases are consequently differentiated by their primary purpose. GLINTT supports nutritional personalisation at the patient level, while DEXTRO supports the organisation and optimisation of care delivery processes.

Collaboration within the final TREAT demonstrator

The final TREAT demonstrator will provide a coordinated presentation of both solutions, with each partner demonstrating the functionality of its own implementation. A common demonstration narrative will explain the healthcare need addressed by each use case, the information it uses, the assistance it provides and its intended users.

This coordinated presentation does not imply a shared application runtime, a common clinical database or an operational connection between the two solutions. Each contribution will be demonstrated within its respective environment, with access managed according to the controls applicable to that environment.

The partners will collaborate on the preparation of demonstration scenarios, the description of their respective contributions and the consolidation of validation evidence for project-level reporting. Technical integration capabilities will be described according to the functionality actually implemented, distinguishing operational interfaces from potential future extensions.

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5.1 Technical Validation

Technical validation will be performed independently for the GLINTT and DEXTRO solutions. Each partner will assess the components, interfaces and data flows included in the version of its demonstrator under evaluation.

The purpose is to verify that each solution operates consistently within its defined technical scope and that its information processing, service behaviour and access controls support the intended demonstration scenarios. Validation evidence will identify the software version, test configuration, input data characteristics, expected behaviour, observed results and relevant limitations.

The independence of the validation environments does not prevent coordinated reporting. Results will be documented using comparable categories where appropriate, while preserving the specific requirements and acceptance criteria of each use case.

- **DEXTRO's** technical validation will focus on the components supporting AI-assisted care pathway processing, structured content generation, conversational interaction and semantic information management.

  The assessment will examine whether the system correctly processes the clinical and care-process documentation used in the demonstration scenarios. Generated outputs will be checked for consistency with their source material, structural correctness and preservation of relevant information. Particular attention will be given to identifying omissions, inconsistencies or unsupported content that could affect the interpretation of a care pathway.

  The validation will also assess the semantic mappings and information exchanges implemented within the solution. Where the demonstrator generates structured process representations, these will be checked against the technical requirements of the implemented formats and tools.

  Service-level testing will cover the behaviour of the implemented interfaces, response times, error handling and access restrictions. The conversational functions will be assessed for their ability to operate within the information and functional scope of the DEXTRO use case. Identified limitations and conditions requiring professional review will be recorded as part of the validation evidence.

- **GLINTT's** technical validation will focus on the processing of patient information and the generation of contextualised dietary recommendations. It will assess whether the clinical, pharmacological and nutritional information supplied to the demonstrator is correctly interpreted and used by the recommendation process.

  Testing will include the handling of incomplete or inconsistent patient information and the identification of situations in which the available data are insufficient to support an adequately contextualised recommendation. The assessment will examine whether relevant patient characteristics and treatment information are reflected in the generated outputs.

  The recommendation components will be evaluated using defined patient profiles and reference scenarios. Testing will focus on the consistency of the relationship between the input information, the relevant clinical knowledge and the resulting dietary recommendations. Where diet–drug–patient interactions are addressed, the corresponding outputs will be checked against the reference criteria established for those scenarios.

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Validation will also examine the traceability of recommendations to the information used to generate them and the consistency of the knowledge representation supporting the implemented functions. Where explanatory information is provided, its correspondence with the recommendation and the underlying patient context will be assessed.

Any connections to FarmaTools, DietTools or other information systems will be evaluated within the scope actually implemented in the validated version. Service-level checks will additionally cover response times, error handling and the access controls applicable to the GLINTT environment.

5.2 Functional Validation

Functional validation will also be organised independently for each partner. It will assess whether the demonstrated functions address the needs of their intended users and provide useful, understandable support within the respective healthcare scenarios.

Each partner will define evaluation scenarios appropriate to its use case and involve relevant professional profiles. The assessment will distinguish between technical correctness, perceived usefulness, usability and clinical or operational appropriateness.

The evidence obtained from both evaluations will be consolidated in the project's validation reporting, while clearly identifying the scope, participants, methods and limitations associated with each solution.

DEXTRO Functional Validation

DEXTRO's functional validation will involve healthcare professionals with knowledge of the care pathways and clinical processes represented in the demonstration scenarios.

The evaluation will assess whether the generated or structured content accurately represents the intended care process and whether it provides useful support for reviewing, defining or organising clinical workflows. Professionals will examine the completeness, clarity and consistency of the outputs, including the identification of content that requires correction or further clinical interpretation.

The assessment will also consider the usefulness of the conversational interaction for accessing and working with care-related information. Usability evaluation will address the ease of completing the selected tasks, the comprehensibility of the interface and the clarity of the information presented.

The resulting evidence will describe how the solution supports professional work within the evaluated scenarios, including its practical limitations and the extent to which outputs require further review before use in a healthcare setting.

GLINTT Functional Validation

GLINTT's functional validation will focus on the appropriateness and usefulness of personalised dietary recommendations in relation to the patient profiles represented in the demonstration scenarios.

Healthcare professionals with expertise relevant to the evaluation will review whether the recommendations take account of the patient's clinical history, pharmacological treatment and nutritional requirements. The assessment will examine whether the outputs are sufficiently specific to the patient context and whether relevant dietary considerations or potential treatment-related interactions are appropriately addressed.

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A further focus will be the clarity of the recommendations and any accompanying explanations. Evaluators will assess whether the information enables professionals to understand the basis of a recommendation, identify its limitations and determine whether it is suitable for discussion with the patient.

Usability evaluation will consider the presentation of patient information, the accessibility of the recommendations and the effort required to review the output within the demonstrated workflow. The evaluation will also examine whether the solution provides practical support for preparing more individualised and understandable dietary guidance.

Conclusions will be based on the evidence collected during the evaluation. Claims concerning improvements in treatment adherence, patient outcomes or treatment discontinuation will only be made where those effects have been specifically measured; they will not be inferred solely from the availability or perceived usefulness of the demonstrator.

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6 Diabetes Monitoring demonstrator

The target outcome of the use case is to develop a prototype of an AI-supported healthcare system that continuously monitors blood glucose levels in diabetes patients, collects ECG, body temperature, blood pressure, and SpO2 data, and integrates with wearable ECG t-shirts developed by Livewell and additional devices. The system will enable long-term, continuous collection of individual health data, which will be evaluated by AI algorithms and shared with other stakeholders.

From ARD studies, through AI-based processing, the system will generate health-related indicators and display them to healthcare professionals via structured dashboards. It will also ensure semantic interoperability with E-Kalite's health intelligence systems, making it possible for clinicians to provide personalized recommendations based on patient-specific information. The demonstrator will be developed in accordance with both GDPR and Türkiye's KVKK legislation.

E-Kalite, on the other hand, plans to build a health intelligence visualization platform that combines information from Livewell's smart t-shirt, Anadolu Sigorta's electronic health records, and WHO datasets. By applying AI models, the platform will produce personalized diabetes risk evaluations and deliver different layers of visualization tailored to various user groups. These will include tools for monitoring data quality for AI developers, patient-oriented views that compare personal risk with similar profiles, interfaces for healthcare professionals showing risk levels against clinical thresholds, executive dashboards for population-based insights, and a public portal presenting diabetes statistics at national and international levels.

In addition to the visualization platform, another key element of the demonstrator is an AI-supported medical recommendation module specifically designed for diabetes care. This component will make use of scanned and unstructured medical documents, including health information forms, epicrisis notes, laboratory reports, imaging reports, and examination documents. Anadolu Sigorta contributes to this module through an AI-supported medical document processing pipeline that applies vision-language models, OCR-supported processing, and natural language processing methods to extract patient-related clinical information and convert it into structured clinical data.

The structured information obtained from these records will serve as the foundation for semantic representation and downstream predictive analysis. Extracted clinical findings such as diagnoses, complaints, laboratory values, imaging-related findings, procedures, and other patient-specific indicators will be semantically enriched and represented in a knowledge graph. This graph will link clinical findings to patients, visits, documents, and source evidence, enabling traceability between AI-generated outputs and the original medical records.

By detecting patterns and risk factors in historical medical documentation, the module will support the generation of patient risk profiles and provide clinicians with AI-supported recommendations and early warning signals concerning diabetes progression and related complications. In this way, Anadolu Sigorta's contribution complements real-time sensor data with structured and explainable clinical knowledge extracted from historical health documents.

Overall, this system will be incorporated into the wider TREAT platform in order to strengthen personalized care pathways and clinical decision-making. Fully aligned with GDPR and Türkiye's KVKK requirements, the demonstrator will support the broader aim of improving patient-specific interventions through interoperable, explainable, and data-driven health intelligence.

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In the first phase, the initial version of a smart t-shirt prototype capable of collecting ECG signals and transmitting them to a mobile device via Bluetooth has been successfully developed. This t-shirt is ready for the integration of basic heart rhythm detection parameters.

To complement this hardware layer, a mobile application will be developed to receive and visualize biosignal data from the wearable device. This app forwards the data to a backend server, where initial analysis modules extract key clinical indicators. ARD has also initiated test integrations with the e-Kalite platform through secure API interfaces. Together, these elements form the foundation for a closed-loop demonstrator system that connects patient monitoring with clinical decision-making tools.

Building on the software and interface layer, E-Kalite has developed visualization mockups for patients, healthcare professionals, and administrators that demonstrate the intended user experience. While not yet connected to real data pipelines, these mockups effectively show how different personas would interact with the system. Additionally, E-Kalite has successfully crawled and visualized WHO diabetes data for the project's public website, providing comparative analyses across different countries and regions. The preliminary work includes:

- Mockups of patient data visualization against reference populations
- Healthcare professional dashboard designs showing risk scores
- Administrative view concepts for population health metrics
- Functioning WHO data visualizations for public awareness

Parallel to these interface efforts, the data management and AI processing infrastructure for the AI-assisted medical recommendation module has been successfully developed. This module is designed to process scanned and unstructured medical records, extract clinically relevant information, and transform these outputs into structured representations that can be used by downstream AI and visualization components.

For unstructured documents, the system employs vision-language models, OCR-supported processing, and NLP techniques to extract structured clinical information. These outputs are then converted into a unified clinical format and prepared for semantic enrichment through the knowledge graph layer.

The Anadolu Sigorta component focuses on generating structured clinical data from heterogeneous medical documents rather than directly retrieving clinical variables from operational database tables. The extracted information is linked to its source document and patient context, enabling evidence-aware patient profiles to be created. These structured outputs are then represented in a semantic graph to support explainable querying, risk profiling, and recommendation generation.

In the subsequent phases of the project, the enhanced prototype (integrating the ECG t-shirt, blood pressure monitor, SpO2 meter, temperature sensor, and glucose meter) will be tested on a limited number of volunteer patients and made accessible to project stakeholders and potential users. The final demonstrator will be presented as part of a pilot field study, fully integrated with the entire system.

The production platform operates within Anadolu Sigorta's secure environment and, in line with KVKK requirements, is not externally accessible. For consortium demonstrations, reviewer presentations, and project documentation, a local digital twin of the platform populated with synthetic patient data is available, replicating the dashboards, medical document processing outputs, semantic graph structure, and conversational AI functionality without exposing real patient documents or identifiable health data. WHO data visualizations remain publicly accessible on the project website.

The LiveWell ECG t-shirt prototype will be made available for controlled pilot testing with selected volunteers and project stakeholders. During the pilot phase, the t-shirt will be used to collect ECG data in

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real-life or semi-controlled environments, supporting the validation of signal acquisition, user comfort, Bluetooth data transfer, and integration with the ARD backend and E-Kalite visualization components.

6.1 Technical Validation

ARD – TREAT Core: ARD's part of the demonstrator is TREAT Core, the central application that evaluates vest and vital-sign measurements and holds the data exchanged between the Turkish partners. It runs as a pilot on the project server and is assessed at TRL 5 (technology validated in a relevant environment). Its requirements in D1.2 were checked as shown below. Response times were measured on the pilot deployment over the project network with a 60-second ECG segment at 250 Hz and a full set of vital signs: 30 sequential requests, then 30 and 40 requests at 5 and 10 concurrent. Each result starts with its status (Validated, Partly validated or Pending); a pending item gives its reason.

Requirement (D1.2)	***Validation***	***Result***
UC4-FR-10 Data standardisation and integration	Integration tests with the LiveWell measurement format, the Anadolu Sigorta clinical data interface and E-Kalite read access	**Partly validated.** Data received from partners (uploaded records, clinical profiles, diabetes risk results) is kept in one record format with owner, read permissions and retention period; vest evaluation results are returned to the caller and not stored. **Pending (pilot):** exchange in the FHIR-based TREAT format over the shared bus (Use Case A), tested once messages flow on the bus.
UC4-FR-11 Critical alerts	Three test sets: normal, moderate and critical vital signs	**Partly validated.** All three sets gave the expected clinical status (0, 2 and 7 alerts). **Pending (pilot):** patient-specific thresholds and notification of clinicians; this version uses fixed clinical thresholds, and alert delivery depends on the dashboards and patient application used in the pilot.
UC4-FR-12 Privacy and compliance	Access tests with separate institution accounts	**Partly validated.** Each institution sees only its own records and those shared with it; an institution without permission is refused. Anadolu Sigorta records carry only a pseudonymous reference, and records are removed automatically when their retention period ends. **Pending (pilot):** patient consent settings and a formal security audit; consent settings need the patient application, and the audit is done before access from outside the project network.
UC4-FR-13 Secure API	API tests with partner accounts	**Validated.** The data and evaluation services require a token and check roles; an institution without permission is refused, and malformed input is rejected. The Anadolu Sigorta clinical data and diabetes risk interface (contract v1.0) is implemented and tested end to end with contract-conformant responses; connecting to the live service requires only its address and credentials.
UC4-FR-14 Patient empowerment tools	–	**Pending (pilot):** requires the patient-facing application, which is not part of TREAT Core.
UC4-FR-15 Analytics and reporting	Review of reports and patient views	**Partly validated.** Reports on processing operations (success rate, response time, credit use); per-patient view of diabetes risk and metabolic values across visits. **Pending (pilot):** clinician feedback on the reports.
UC4-NFR-05 Performance and scalability	Load test with 1, 5 and 10 concurrent evaluation requests	**Partly validated.** No failed requests at any load. The analysis service handles one evaluation at a time (about 0.7 per second), so waiting time grows with simultaneous requests: 95th percentile 1.6 s single, 11.2 s with 5 and 17.5 s with 10 concurrent requests. **Pending (pilot):** parallel evaluation for higher volumes, measured again with pilot traffic.

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UC4-NFR-06 Secure data management	Configuration review	**Partly validated.** Access is limited to registered network addresses, with token-based authentication. **Pending:** encrypted transport (HTTPS), encryption at rest and a security audit, set up before any access from outside the project network.
UC4-NFR-07 Availability	Restart and update tests	**Partly validated.** Services start automatically; the analysis service returned about 15 s after an unexpected stop; two updates were applied with backup and rollback, without data loss. **Pending (pilot):** uptime against the 99.9 % target, which needs an extended observation period.
UC4-NFR-08 Usable interfaces	Review of the operator console	**Partly validated.** Light and dark display, table views alongside charts, keyboard access to chart values. **Pending (pilot):** usability tests with users.
UC4-NFR-09 Interoperability with partner systems	API tests with the accounts and data formats of Anadolu Sigorta, E-Kalite and LiveWell	**Validated for accounts and data formats. Pending (pilot):** tests with the partners' own live systems.
UC4-NFR-10 Low latency	Response-time measurement	**Validated.** A 60-second ECG segment with vital signs is evaluated in a median 1.4 s (95th percentile 1.6 s); reading a shared record takes a median 21 ms (95th percentile 32 ms).
UC4-NFR-11 Modular design	Code review and update tests	**Validated.** Separate services for data, processing and partner exchange; a partner link switches from test to live operation by configuration; two updates were applied during validation without data loss.

E-Kalite – Health Intelligence Platform: E-Kalite's part of the demonstrator is the analytics and conversational layer: four dashboards (Clinical, Alert, Patient, Data Quality) and a Turkish natural language query interface, built on TURBOARD and reading the TREAT database in read-only mode. It runs in Anadolu Sigorta's secure environment and is assessed at TRL 5. Since that environment is closed under KVKK, validation was carried out on the local digital twin described above, populated with synthetic Turkish health data that mirrors the production schema.

Requirement (D1.2)	***Validation***	***Result***
UC4-FR-05 Real-time visualisation of diabetes metrics	Review of the four dashboards against reference datasets	Validated. Glucose and HbA1c trends, risk distribution, treatment effectiveness and AI-predicted risk levels are presented per user profile. Each dashboard opens with an automatically generated written summary of the most significant finding.
UC4-FR-06 Interactive features for healthcare	Drill-down tests on the clinical and data quality dashboards	Validated. Indicators can be broken down by data source, document type and time. Clinicians can also ask follow-up questions in Turkish on the same screen, keeping the context of the summary above. Pending (pilot): feedback from practising clinicians.
UC4-FR-07 Patient engagement visualisations	Scenario tests on the patient dashboard	Partly validated. Personal blood pressure, body mass index, HbA1c and risk score are shown with the patient's own trajectory, described in second person with one weekly behavioural suggestion. Pending (pilot): usability tests with patients.
UC4-FR-11 Critical alerts system	Three test sets with normal, moderate and critical values	Partly validated on the dashboard side. Patients crossing clinical thresholds are detected, classified by alert type and listed individually with visual priority. Pending (pilot): patient-specific thresholds and

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		notification delivery, which depend on components outside the dashboards.
UC4-FR-12 Data privacy and compliance	Configuration review	Partly validated. The platform holds no patient records of its own and reads the TREAT database in read-only mode. All consortium demonstrations and screenshots come from the synthetic environment. Pending (pilot): patient consent settings and a formal security audit.
UC4-FR-13 Secure API	Integration tests against the TREAT Core interfaces	Validated from the E-Kalite side. Clinical profiles and diabetes risk results are read with E-Kalite's own account; requests without permission are refused.
UC4-FR-14 Patient empowerment tools	Review of the patient dashboard	Partly validated. Progress tracking against the patient's own history and a personalised weekly suggestion are in place. Educational modules, medication reminders and goal setting sit outside the E-Kalite component.
UC4-FR-15 Health data analytics and reporting	Comparison of generated output against the source data slice	Validated. Metric values match the source records and the selected headline matches the most significant deviation in the test sets. Data quality reporting covers completeness, consistency, validity and timeliness, with issues classified by severity. Pending (pilot): clinician feedback on report usability.
UC4-NFR-02 Dashboard accessibility and responsiveness	Review across desktop and tablet widths	Partly validated. Layouts adapt to the display, charts are paired with table views and chart values are reachable from the keyboard. Pending: formal WCAG compliance check.
UC4-NFR-03 Scalable architecture	Measurement on the digital twin	Partly validated. Dashboards and generated summaries load within the target time at the data volumes tested. Pending (pilot): measurement under production data volumes and concurrent users.
UC4-NFR-08 User-friendly interfaces	Review against the persona definitions	Partly validated. Seven user profiles are configured, each with its own screen template, terminology and depth of detail. The same clinical finding is expressed in clinical language for a specialist and in plain language for a patient. Pending (pilot): usability tests with target user groups.
UC4-NFR-09 Interoperability with diverse systems	Integration tests with TREAT Core and the Anadolu Sigorta clinical data interface	Validated for accounts and data formats. Dashboards embed into the Clinical Command Center through iframe and API integration points, with authorisation aligned to its role-based structure. Pending (pilot): tests against the partners' live systems.

Anadolu Sigorta – Patient Diabetes Risk Profile Platform: Anadolu Sigorta's part of the demonstrator provides the clinical data processing and AI intelligence layer for the Turkish use case. The solution processes heterogeneous health documents using a hybrid pipeline combining rule-based methods, Vision-Language Models (VLMs) and Large Language Models (LLMs) for document classification, OCR and structured clinical information extraction. Extracted information is normalised and mapped to standard clinical terminology, consolidated into longitudinal patient profiles, and used by downstream services for diabetes-related risk assessment. The services are deployed and tested within Anadolu Sigorta's secure environment and exposed to the TREAT platform through controlled APIs. Due to KVKK and internal data-security restrictions, consortium-level demonstrations use synthetic or appropriately protected test data following the same structures and processing interfaces as the target environment.

Requirement (D1.2)	***Validation***	***Result***
UC4-FR-09 – Data Management System for AI Modules	Patient-profile generation tests using historical medical information extracted from multiple clinical documents belonging to the same person	**Validated at prototype level.** Historical clinical information is retrieved and transformed into a structured patient profile containing demographic information and a longitudinal clinical timeline. The profile combines information such as complaints, medical history, examination findings, laboratory results, diagnoses and treatments and can be provided

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		to downstream AI modules for patient profiling and medical decision support. **Pending (pilot):** evaluation with larger longitudinal patient histories and end-to-end use by the final AI modules.
UC4-FR-10 – Data Standardization and Integration in AI-CDSS	Evaluation of the common patient-profile structure and terminology mapping of extracted clinical information	**Partly validated.** Heterogeneous clinical documents are converted into a common structured representation before being provided to downstream services. Extracted concepts are additionally linked to standard clinical terminology, including ICD-10 for diagnoses, LOINC for laboratory concepts and ATC for medication-related information. This reduces dependence on hospital- or document-specific source formats. **Pending (pilot):** end-to-end validation against the final interoperability specifications and interfaces adopted by the TREAT platform.
UC4-FR-13 – Secure API Development	Integration tests between Anadolu Sigorta's clinical data services and external TREAT components	**Partly validated from the Anadolu Sigorta side.** Structured patient profiles and related clinical information are exposed through controlled REST service interfaces so that authorised TREAT components can consume the required information without accessing Anadolu Sigorta's underlying data repositories or original clinical documents. **Pending (pilot):** bilateral integration and security validation with the final AI-CDSS interfaces.
UC4-NFR-04 – High-Performance Scalable Data System	Architectural and component-level review of the clinical data processing and patient-profile pipeline	**Partly validated.** Document classification, OCR, clinical information extraction, terminology mapping and patient-profile generation are implemented as separate processing components and services. This modular structure allows individual stages to be updated and scaled independently and supports asynchronous preparation of patient profiles before they are requested by downstream AI services. **Pending (pilot)**: performance, scalability and reliability testing under production-scale document volumes.
UC4-NFR-09 – Interoperability with Diverse Systems	Tests of the structured patient-profile format and API-based exchange with downstream components	**Validated at prototype level.** Anadolu Sigorta converts heterogeneous internal clinical information into a common representation that can be exchanged with other TREAT components through defined service interfaces. Standard terminology mappings further reduce source-specific dependencies and support semantic interoperability. **Pending (pilot)**: end-to-end API and data-format validation with the final deployed systems of the national consortium partners.

6.2 Functional Validation

ARD – TREAT Core: ARD's part was validated with the partner institutions as its users, in the scenarios the demonstrator is built for:

- **Vest data evaluation (LiveWell format):** a measurement package returns heart-rate variability features, alerts, clinical status and stroke-risk level in the same response. When the ECG part cannot be processed, the other results are still returned; malformed input is rejected.
- **Clinical profile and diabetes risk (Anadolu Sigorta → TREAT → E-Kalite):** a patient is enrolled with a pseudonymous reference; the profile and risk are collected when ready and stored with Anadolu Sigorta as owner and read access for E-Kalite, which reads them with its own account. An institution without permission is refused.

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- **Data sharing between institutions:** a record owned by one institution and shared with another is found and read by that institution; institutions without permission receive no rows and are refused.
- **Operation:** ARD operators follow each patient's progress and every exchange with the partner service from a console.

Step-by-step guides were prepared for LiveWell and Anadolu Sigorta, and their examples were run against the pilot deployment. Validation with clinicians and patients takes place in the pilot with volunteer patients described above, using the evaluation means defined in D1.2: usability tests and feedback on alerts, reports and privacy controls.

E-Kalite – Health Intelligence Platform. E-Kalite's part was validated against the scenarios each user profile is built for:

- **Population review (clinical dashboard):** a specialist opens the dashboard and reads a generated summary of risk concentration, HbA1c trend and treatment effectiveness, then asks a follow-up question in Turkish without leaving the screen.
- **Critical case triage (alert dashboard):** patients crossing clinical thresholds are detected, classified by alert type and listed individually, with the generated summary naming the single action to take first.
- **Personal trajectory (patient dashboard):** the same engine produces a second-person account of the patient's own measurements in simplified language, with one weekly behavioural suggestion.
- **Quality monitoring (data quality dashboard):** a data specialist traces a drop in a quality score back to the source and document type that caused it.
- **Profile separation:** the same data slice was run through each profile. The selected finding and the language differ by profile, and no profile returns data outside its authorisation.

Scenario scripts were run against the digital twin and the findings fed back into the prompt design. Validation with clinicians and patients takes place in the pilot described above, using the means of evaluation defined in D1.2: usability tests and feedback from healthcare professionals and patients.

Anadolu Sigorta – Patient Diabetes Risk Profile Platform: Anadolu Sigorta's part was validated through the end-to-end scenarios in which historical clinical information is prepared for use by the TREAT AI modules:

- **Clinical document processing:** heterogeneous Turkish health documents, including patient information forms, epicrisis reports, laboratory reports and imaging reports, are classified and processed through the appropriate text- or vision-based path. The extracted content is converted into structured clinical information rather than being exposed as raw documents.
- **Longitudinal patient profile generation:** clinical information extracted from multiple documents belonging to the same person is consolidated into a common patient profile. Demographic information is kept together with a chronological clinical timeline containing findings such as complaints, medical history, examinations, laboratory results, diagnoses and treatments.
- **Clinical terminology mapping:** extracted diagnoses, laboratory concepts and medication-related information are linked, where applicable, to standard terminology such as ICD-10, LOINC and ATC. The resulting standardised information can be consumed independently of the original hospital or document format.
- **Diabetes-related assessment:** the structured profile is evaluated using diagnosis information, diabetes-related laboratory findings, medical history and available family-history evidence. The service distinguishes confirmed diabetes, preliminary or suspected diabetes, and patients presenting relevant risk indicators, while retaining the clinical evidence supporting the result.

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- **TREAT integration (Anadolu Sigorta → TREAT):** patient profiles and derived results are exposed through controlled service interfaces. The TREAT platform can retrieve the structured profile and use it as input for downstream risk, recommendation and visualisation components without requiring access to Anadolu Sigorta's original clinical documents or internal data repositories.
- **Profile preparation before downstream use:** since extraction of historical documents may take longer than an interactive request, profile generation can be initiated when a patient is enrolled and prepared in advance. Downstream TREAT services can then retrieve the structured clinical profile when it becomes available.

The scenarios were tested with representative clinical documents and patient-profile examples in Anadolu Sigorta's controlled environment. The generated structured profiles and diabetes-related evidence were reviewed against the corresponding source information, and the service interfaces were exercised as part of the TREAT integration flow. Further validation during the pilot will focus on larger longitudinal patient histories, end-to-end partner integration and clinical assessment of the diabetes-risk and recommendation outputs.

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7 Distributed Diagnoses and Home Healthcare demonstrator

The demonstrator developed within the TREAT project aims to enable remote and continuous monitoring of patients integrated into (i) Cardiac Rehabilitation Programs (CRP), (ii) Paediatric Diabetes, and (iii) Paediatric Obesity, ensuring the collection, monitoring, and analysis of relevant clinical data both inside and outside the hospital environment.

Through integrated devices (such as blood pressure monitors, smart scales, continuous glucose monitoring devices, etc.), it is possible to collect vital parameters and automatically transmit them to the clinical team through the patient mobile app, ensuring real-time distributed diagnostic assistance and personalized home care.

This demonstrator also includes a mobile app for patients, with features such as alert notifications, medication reminders, appointment/exam scheduling, and recommendations based on clinical progress, fostering greater adherence to the program and empowering patients in managing their health.

Referrals to the Cardiac Rehabilitation Program (CRP) can be made through different pathways, depending on the phase of the program in which the patient is enrolled. The CRP is structured in two main phases: Phase I and Phase II.

Patients are typically referred to Phase I following an acute cardiac event that results in hospital admission. Each day, nurses review the list of inpatients with cardiac pathology using the HER system, identifying candidates for rehabilitation. After assessing clinical stability and the patient's capacity to participate in exercise, eligible patients are referred to Phase I and begin rehabilitation sessions.

Referral to Phase II may occur at the end of Phase I, or by the family physician if the cardiac event took place outside ULSTMAD. In this phase, a cardiologist reviews the clinical information available in the EHR system and determines whether the patient meets the criteria to join the program.

Once the referral is accepted, the patient progresses through a series of consultations, including cardiology, nursing, and physiatry, and undergoes complementary exams before joining a rehabilitation group. These steps, currently performed at different stages, will be centrally recorded in the Individual Integrated Care Program (ICP).

This digital platform will ensure that, according to assigned permissions, all healthcare professionals involved have timely and efficient access to the patient's clinical information. During rehabilitation sessions, clinical and functional parameters are recorded according to the program phase:

- Phase I: Heart rate, oxygen saturation, blood pressure, exercise sets, and repetitions.
- Phase II: Heart rate, oxygen saturation, blood pressure, weight, BMI, abdominal circumference, blood glucose, and peak values of heart rate, blood pressure, and oxygen saturation during training.

All records will be entered digitally in the ICP platform, centralizing information, facilitating real-time access and updates by the care team, and supporting continuous clinical monitoring through graphical tools and automatic reports. Patient progress is further monitored by comparing responses to questionnaires administered at different time points (initial assessment, Mediterranean diet adherence, quality of life, final assessment, and satisfaction with nursing care).

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Referrals for a child to attend the First Multidisciplinary Pediatric Obesity Consultation can be made by any in-house physician using the EHR system, or by primary care physicians through the platform.

During the consultation in which the patient is referred, the attending physician may record indicators such as Z-score, BMI, weight, height, and age. However, referrals may also be submitted without these indicators, relying solely on the clinical summary of the patient. Nonetheless, it is crucial that any referral includes relevant clinical information to ensure the multidisciplinary team has the necessary data for an appropriate and effective assessment.

Once the referral is submitted, a pediatric triage physician reviews the clinical information to determine whether the patient meets the criteria for scheduling the First Multidisciplinary Pediatric Obesity Consultation.

This initial consultation involves coordinated assessments by Nursing, Nutrition, Psychology, and Pediatrics, and leads to a referral to an Individual Care Plan (ICP). The ICP serves both as a dynamic, patient-centered roadmap for follow-up and intervention, ensuring that care is structured, goal-oriented, and adapted to the child's evolving needs, and as a clinical record platform that centralizes personal data, medical history, educational content, and standardized scales and questionnaires.

The process is supported by interoperability between several EHR systems, allowing multidisciplinary team centralized access to health records and progress updates. This integration significantly enhances continuity of care and facilitates coordinated decision-making. As consultations progress, professionals will have access to updated clinical data, enabling comparisons across visits and supporting more accurate monitoring of health indicators.

At present, there is no formal referral process in place at ULSTMAD for the first multidisciplinary consultation for childhood diabetes. Typically, referrals occur when a child is seen by the attending physician during an emergency department visit due to a symptomatic presentation.

Upon arrival at the emergency department, the patient registers at the administrative desk, where staff record the visit and create a clinical episode. The triage nurse then evaluates the child and classifies the severity of the case using the Manchester Triage System, assigning a priority wristband accordingly. The patient is then assessed by the Emergency Physician, who performs clinical evaluation and diagnosis. In cases of Type 1 Diabetes Mellitus (T1DM), hospitalization in the Pediatrics Department is required. At discharge, the physician informs the caregivers that the child will be followed in Pediatric outpatient consultations within the scope of the multidisciplinary diabetes care program.

This initial consultation involves coordinated assessments by Nursing, Nutrition, Psychology, and Pediatrics, and is formally referred and integrated into the Individual Care Plan (ICP). As with the process for Pediatric Obesity, the ICP serves as a dynamic and patient-centered roadmap for follow-up and intervention, ensuring that care is structured, goal-oriented, and tailored to the child's evolving clinical and psychosocial needs.

The process is supported by interoperability between several systems, allowing the multidisciplinary team centralized access to health records and real-time updates. This integration significantly enhances continuity of care and facilitates collaborative, informed decision-making. As consultations progress, healthcare professionals will have access to updated clinical records, enabling longitudinal comparisons across visits and more accurate monitoring of clinical indicators.

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7.1 Technical Validation

ByMe / ULSTMAD – Individual Care Plan (ICP): The Portuguese demonstrator was validated against the UC5 functional and non-functional requirements of D1.2 through walkthroughs of the three care programmes (cardiac rehabilitation, paediatric obesity and paediatric type 1 diabetes) in the ICP platform at ULSTMAD, integration tests with the hospital and primary care systems (SONHO, SClínico, bHealth, SR SIGA), and a FHIR ingestion test within the TREAT Complete scenario. Each result below begins with its validation status; outstanding items are identified explicitly.

Functional requirements

Requirement (D1.2)	*Validation*	*Result*
UC5-FR-01 – DM1 Hospitalization	Review of the DM1 pathway from the emergency episode and hospitalisation (SONHO, SClínico) to referral into the multidisciplinary programme in the ICP.	**Partly validated.** The emergency episode and the hospitalisation remain recorded in SONHO and SClínico. At discharge the child is referred to the multidisciplinary diabetes programme and the ICP is opened, with administrative and clinical data imported automatically. The structured written education given to the child and caregivers (disease management, carbohydrate counting, blood glucose monitoring) is recorded by the paediatrician in the ICP. **Pending:** the evaluation metrics defined in D1.2 (length of hospitalisation, caregiver understanding of the disease) were not measured during the project.
UC5-FR-02 – DM1 Multidisciplinary Consultations	Verification that successive multidisciplinary consultations are scheduled and recorded in the ICP, and that data can be compared across visits.	**Pending.** It's still not live, however it's been proven with the cardiac rehabilitation ICP that professionals see the updated data from previous visits, so the treatment plan can be adjusted as intervals between consultations increase.
UC5-FR-03 – DM1 Multidisciplinary Team	Review of the role-specific forms available in the ICP for each professional and of the predefined consultation path.	**Validated (workflow).** The ICP provides standardised forms for the nurse (Medical and Nursing Records Form), nutritionist (anthropometric and biochemical assessment including HbA1c, 24-hour dietary recall, dietary intervention), psychologist (anamnesis, psychological and behavioural assessment of child and caregivers) and paediatrician (clinical evaluation and education). **Pending:** the impact on glucose control and psychological well-being requires CGM integration and a longer observation period.
UC5-FR-04 – DM1 Educational Approach	Review of how education is delivered and documented, and of age-adapted content for the child.	**Partly validated.** Structured education is delivered to the child and caregivers in written form and documented in the ICP. **Pending:** age-adapted educational and motivational content for the child, planned for the patient mobile app.
UC5-FR-05 – DM1 Integration	Review of support for the child's integration into the school environment.	**Not validated.** School integration (Could Have) is outside the scope of the final demonstrator and remains a candidate for future extension.

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Requirement (D1.2)	*Validation*	*Result*
UC5-FR-06 – DM1 Communication	Review of the communication channels between the multidisciplinary team and the parents.	**Partly validated.** All professionals share one record of the child's follow-up in the ICP, which improves the flow of information within the team. **Pending:** a direct channel between caregivers and the team through the patient app, and the inter-professional chat suggested during the requirement sessions.
UC5-FR-07 – OBS Referral	Walkthrough of the referral and triage workflow across SClínico, SR SIGA and the ICP.	**Validated.** Referrals are made by in-house physicians in SClínico and by primary care physicians through SR SIGA. The paediatric triage physician reviews the clinical information and authorises or declines the First Multidisciplinary Paediatric Obesity Consultation, after which the child is referred to the ICP.
UC5-FR-08 – OBS Diagnosis	Verification that Z-score and BMI are captured and available to assess obesity severity.	**Partly validated.** Z-score, BMI, weight, height and age can be recorded at referral, and the nutritionist records anthropometry (weight, height, BMI percentile) in the ICP at each visit. **Pending:** automatic classification of severity against the D1.2 thresholds (Z-score > 2 and > 3. To be implemented until the end of the year.
UC5-FR-09 – OBS Multidisciplinary Consultations	Verification that the sequential consultation path is implemented in the ICP.	**Validated.** The ICP implements the sequence nursing, nutrition, psychology and paediatrics, each with its own standardised form. Feedback from the professionals on this sequence is reported in the functional validation below.
UC5-FR-10 – OBS Hospitalization	Review of support for inpatient education in extreme cases.	**Not validated.** Hospitalisation in extreme cases remains managed in SClínico; the demonstrator does not include a dedicated inpatient education module for obesity.
UC5-FR-11 – OBS History	Review of the forms used to record family history and psychological factors.	**Validated.** The nutritionist records personal and family medical history related to obesity, sleep, screen time and physical activity, and the psychologist completes a detailed anamnesis and a psychological and behavioural assessment of the child and caregivers.
UC5-FR-12 – CR Phase I Inpatient	Walkthrough of Phase I referral and session recording in the ICP.	**Validated.** Nurses identify Phase I candidates from the inpatient list in SClínico. During sessions, heart rate, oxygen saturation, blood pressure, exercise sets and repetitions are recorded digitally in the ICP, replacing paper records.

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Requirement (D1.2)	*Validation*	*Result*
UC5-FR-13 – CR Phase II Outpatient	Walkthrough of Phase II referral, consultations, and session recording; test of device data ingestion for telemonitoring.	**Partly validated.** Phase II referral, consultations (cardiology, nursing, physiatry), complementary exams and in-hospital session parameters (heart rate, SpO2, blood pressure, weight, BMI, abdominal circumference, blood glucose and training peaks) are recorded in the ICP, with progress comparison embedded in the forms and automatically generated PDF reports. Ingestion of device metrics (blood glucose, heart rate, weight, SpO2) as FHIR resources into the ICP was demonstrated in the TREAT Complete scenario, in a sandbox with synthetic data. **Pending:** production integration of the PLUX wearables and connected devices for home-based telemonitoring.
UC5-FR-14 – CR Phase III Maintenance	Review of support for long-term remote maintenance monitoring.	**Not validated.** Phase III is not yet established at ULSTMAD. The device-ingestion endpoints developed for Phase II provide the technical basis for future remote maintenance monitoring.

Non-functional requirements

Requirement (D1.2)	*Validation*	*Result*
UC5-NFR-01 – Security	Review of hosting, access control and data protection measures; security audit and penetration testing.	**Partly validated.** The ICP runs on ULSTMAD infrastructure. Access is differentiated by professional profile (e.g. nurse, cardiologist, physiatrist, administrative staff), so each user only views and edits the information relevant to their role. Exchanges with other TREAT platforms in the TREAT Complete scenario used synthetic data and static FHIR files, with no live connection to production systems.
UC5-NFR-02 – Usability	Usability testing, continuous feedback, accessibility testing, usage data analysis.	**Partly validated.** The interface was designed with the clinical teams, with profile segmentation and simplified navigation per role. Feedback on the preliminary demonstrator led to UX/UI optimisations that streamline workflows and reduce friction. **Pending:** formal usability testing (e.g. SUS questionnaire) and accessibility testing, in particular of the patient-facing app.

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Requirement (D1.2)	*Validation*	*Result*
UC5-NFR-03 – Interoperability	Integration tests with hospital and primary care systems; FHIR ingestion test against the WP4 FHIR interoperability specification.	**Validated for institutional systems; validated at proof-of-concept level for FHIR.** The ICP integrates with SONHO, SClínico, bHealth and SR SIGA, importing administrative and clinical data (name, date of birth, gender, marital status, patient number, profession, contact details, address) without manual re-entry. The ICP also consumes FHIR resources produced by other TREAT platforms, following the WP4 FHIR interoperability specification, and maps them to ICP fields (blood glucose, heart rate, weight, SpO2) in the first-consultation form while the patient is in the "In treatment" state. **Limitations:** in the proof of concept, data is parsed from static FHIR batches rather than a live exchange, and patient identity matching is not resolved (a single pre-created patient is used).
UC5-NFR-04 – Reliability	Failure tests, downtime analysis, resilience audits, performance testing.	**Validated.** The ICP is deployed on ULSTMAD infrastructure, for which D1.2 specifies active-active operation between two local datacentres and the ULSTMAD cloud, backups and a disaster recovery plan.
UC5-NFR-05 – Feedback	Feedback functionality testing; analysis of system interactions.	**Partly validated.** For professionals, progress feedback is given through comparisons embedded in forms, graphical tools and automatically generated reports. The CRP includes questionnaires at different points in time (initial assessment, Mediterranean diet adherence, quality of life, final assessment, satisfaction with nursing care). **Pending:** immediate patient-facing feedback and automatic questionnaire reminders through the patient app.
UC5-NFR-06 – Customization	Customization testing; patient adherence analysis with customised features.	**Validated (configuration).** The same ICP platform was configured for three care programmes (cardiac rehabilitation, paediatric obesity, paediatric diabetes), each with its own clinical parameters, forms, questionnaires and consultation path. **Pending:** analysis of patient adherence with customised features.

In summary, the clinical workflows of the three programmes (FR-02, FR-03, FR-07, FR-09, FR-11, FR-12) and the integration with the institutional systems are validated. Requirements that depend on home-based data collection (FR-13 telemonitoring, FR-14) and on the patient app (FR-04, FR-06, NFR-05) are partly validated or pending, since wearable and device integration with PLUX and the patient app only started in 2026. Two requirements (FR-05, FR-10) were outside the scope of the final demonstrator.

7.2 Functional Validation

ByMe / ULSTMAD – Individual Care Plan (ICP): Functional validation in the Portuguese use case was carried out with the ULSTMAD clinical teams throughout the project, following the methodology defined in D1.2, in which the Clinical Multidisciplinary Group (MG) and the Medical Informatics development team (MI) work together. Validation took place in three stages:

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- **Co-creation and requirement validation (2024):** multidisciplinary meetings with the teams of each programme, observation of a cardiac rehabilitation training session, and presentation of the AS-IS BPMN models to the multidisciplinary groups for review and validation.
- **Iterative validation in clinical use (2025–2026):** the preliminary demonstrator was made available at ULSTMAD in real clinical context, and the feedback of the professionals was fed back into development.
- **Validation of the final demonstrator (2026):** acceptance of the final workflows by the clinical teams and end-to-end walkthroughs of the demonstrator scenarios with clinical professionals.

The table below lists the validation sessions and their main outcomes.

Date	***Participants***	***Scope and main outcomes***
15/10/2024	Paediatric DM1 clinical team	Mapping of the DM1 pathway from emergency diagnosis to outpatient follow-up; education during hospitalisation; role of each professional; communication with parents.
23/10/2024	Paediatric DM1 clinical team	Need for structured communication between professionals (chat suggested); use of the Libre CGM device and insulin pumps; nurses' role in teaching glucose monitoring.
16/10/2024	Paediatric obesity clinical team	Referral and monitoring process, records in SClínico; interest in an app with step counter and healthy-habit monitoring.
04/11/2024	Paediatric obesity clinical team	Triage based on Z-score and BMI; follow-up and exit criteria (discharge, continued follow-up, age 18); app features (food tracking, periodic weighing, connected devices).
24/10/2024	Cardiac rehabilitation team	Limitations of paper records; requirements for a digital platform to centralise data; device kit for participants; home monitoring.
13/11/2024	Cardiac rehabilitation training session (observation)	Nurses spend significant time recording data manually on paper and in SClínico, confirming the need for digital recording and device integration.
[May 2025]	Multidisciplinary groups (all programmes)	Validation of the AS-IS BPMN models of the three programmes, used as the basis for the ICP configuration.
[June 2025 – June 2026]	Clinical users of the preliminary demonstrator at ULSTMAD	Use of the preliminary ICP in real clinical context; feedback led to refactoring of the algorithms that cross-validate clinical input forms and to UX/UI optimisations.
[Sept 2026 – Oct 2026]	4 profiles and 13 professionals.	Acceptance of the final ICP workflows before go-live in production.
[Oct–Nov 2026 – dates]	ULSTMAD clinical professionals (nurse, cardiologist, physiatrist, administrative staff; paediatric team)	End-to-end walkthroughs of the demonstrator scenarios for the final review

Requirement validation (2024). The sessions confirmed the clinical pathways of the three programmes and produced the needs listed in D1.2. Across programmes, the teams pointed to the same issues: information scattered across paper and several systems, duplicated recording by nurses, and the lack of a shared view of the patient for the whole multidisciplinary team. These findings set the priorities of the ICP:

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one shared record per patient, role-specific standardised forms, automatic import of data from SONHO and SClínico, and progress comparison across visits.

Iterative validation in clinical use (2025–2026). Use of the preliminary demonstrator by the ULSTMAD professionals led to two main changes in the final demonstrator: refactoring of the algorithms used to compare and reconcile clinical forms across time points, and UX/UI optimisations to streamline workflows. [ULSTMAD to add the main feedback points from clinical users, e.g. time saved in recording, ease of finding information, issues raised.]

Validation of the final demonstrator (2026). For the final review, the demonstrator scenarios were executed end to end by ULSTMAD clinical professionals on the real hospital systems (SClínico, SONHO, SR SIGA and ICP), in a sandbox environment with synthetic patient data:

- **Cardiac rehabilitation:** an adult patient journey through referral, Phase I and Phase II, performed by the professionals involved in the programme (nurse, cardiologist, physiatrist, administrative staff) and recorded on video with an adult volunteer.
- **Paediatric obesity and paediatric diabetes:** synthetic patient journeys shown as screen recordings with narration by the clinical professionals. No minors took part, avoiding consent and parental authorisation issues.
- **Cross-country interoperability (TREAT Complete):** the ICP received device metrics (blood glucose, heart rate, weight and SpO2) from other TREAT platforms as FHIR resources and displayed them in the first-consultation form. This shows how the ICP can fill the gap left by the lack of approved glucose monitoring devices integrated into the ICP.

Patients and caregivers. Validation with patients and caregivers is not yet complete. D1.2 and D1.4 foresee validation in a real-world setting with patients in home rehabilitation, which depends on the production roll-out of the PLUX wearables, the connected devices and the patient app. This validation will continue after the end of the project.

Overall, the technical and functional validation shows that the Portuguese demonstrator has established the core of the ICP described in D1.2: a shared, multidisciplinary care plan for three programmes, integrated with the institutional systems of ULSTMAD and able to consume standardised FHIR data from other TREAT platforms. The clinical teams were involved from requirement definition to the final demonstration. The main open items are home-based telemonitoring with wearables and devices in production, the patient-facing app, and formal usability, security and reliability evidence, which will be completed after the project as the solution is rolled out in clinical practice.

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8 Enhancing Patient Self-Efficacy and NCD Management through AI-Powered Remote Monitoring demonstrator

The Well@Home demonstrator focuses on enhancing patient self-efficacy and improving the management of non-communicable diseases (NCDs) through AI-powered remote monitoring and clinical decision support within the Well@Home platform.

The demonstrator combines descriptive, predictive, and prescriptive AI functionalities to support healthcare professionals in patient monitoring, risk identification, and recommendation management. The first stage focuses on enhanced visualizations and trend-based monitoring within the Clinical Command Center (CCC) and Alerts Dashboard. The second stage introduces predictive AI models capable of identifying potential disease trajectories using anonymized patient data from partner hospitals. The third stage introduces AI-assisted recommendations and educational support functionalities.

The system is designed to support longitudinal patient monitoring while taking the patient's broader clinical context into account rather than focusing on a single medical specialty. The project currently remains mostly in the research phase, with potential market introduction foreseen approximately two years after project completion and subject to healthcare regulatory requirements and validation procedures.

The final demonstrator is planned as an integrated AI-supported remote monitoring and recommendation environment within the Well@Home platform.

The demonstrator includes enhanced visualization capabilities within the Clinical Command Center (CCC) and Alerts Dashboard, supporting healthcare professionals in identifying evolving patient conditions and trends approaching clinically relevant thresholds. Both step-based and slope-based trend visualizations are being explored to improve interpretation of longitudinal patient data.

The platform also integrates the Early Warning Score (EWS) as a measurement type within the existing measurement framework, including dashboard visualization and manual measurement workflows for healthcare professionals and patients.

The predictive AI layer focuses on identifying elevated patient risk for non-communicable diseases using anonymized patient data from partner hospitals. Predictions are based on International Disease Codes (IDC) and are planned to be displayed within patient profiles and dashboard environments.

The demonstrator also includes a patient tagging system based on questionnaire data and patient information. These tags are intended to support recommendation logic, educational article matching, and future AI-supported workflows.

The prescriptive component is based on a recommendation engine integrated into the Well@Home education module. The recommendation engine combines predictive outputs with educational articles and rule-based clinical guidance to support personalized lifestyle recommendations. Educational articles can be grouped into assignable article sets. These sets can be matched to disease codes and assigned to patients as a single unit within the platform workflows. The recommendation engine uses these relationships to support AI-assisted recommendation and educational content selection.

All AI-generated recommendations and educational suggestions require validation by healthcare professionals before being shared with patients.

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The demonstrator further emphasizes transparent AI integration, ensuring that AI-generated predictions and recommendations remain clearly distinguishable from clinically confirmed diagnoses.

The demonstrator is being developed as an integrated component of the Well@Home platform. Healthcare professionals access the demonstrator functionalities through existing platform environments, including the Clinical Command Center (CCC), Alerts Dashboard, patient profiles, measurement workflows, and education module.

Patients access assigned educational articles, measurements, and notifications through the existing Well@Home patient application.

The AI and recommendation functionalities are currently intended for controlled project usage, testing, and validation activities within the TREAT project environment.

The consortium aims to have all required framework components, integrations, and demonstrator functionalities in place by the end of the TREAT project in order to showcase the complete demonstrator workflow during the final TREAT review. This includes the end-to-end integration of visualization components, predictive AI workflows, recommendation support mechanisms, and educational content matching within the Well@Home platform environment.

Due to the delayed funding approval and later project start of the Belgian consortium compared to the overall international TREAT project timeline, part of the local development and refinement activities will continue beyond the formal end of the international TREAT project. While the required demonstrator components and technical framework are expected to be operational for the final project review, additional post-project work is expected to further fine-tune and validate the underlying AI models powering the predictive insights and recommendation functionalities.

8.1 Technical Validation

BeWell – Well@Home AI-powered remote monitoring: The Belgian demonstrator was validated against the non-functional requirements of D1.2 through review of the Well@Home platform architecture, its quality management system, and the integration of the AI and recommendation components into the existing platform environment. Well@Home is developed under an ISO 13485-certified quality management system and an IEC 62304 software life cycle, which provides the baseline for the privacy, security and reliability controls reported below. Because the Belgian consortium started later than the international project, several AI-specific validations are planned for the remaining project period and are marked as pending. Each result below begins with its validation status; outstanding items are identified explicitly.

REQUIREMENT (D1.2)	***VALIDATION***	***RESULT***
UC6-NFR-01 – Data Privacy	Compliance review of storage, transmission, access control and AI data processing against GDPR and healthcare regulations.	Validated. Patient data in Well@Home is encrypted in transit and at rest, protected by role-based access control, and processed under the ISO 13485 quality management system. AI model development uses anonymised data from partner hospitals; training runs on the hospital's own infrastructure, so the data does not leave the hospital environment. A security, privacy and ethics check was carried out during

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		delivery of the AI/ML algorithm. Pending: the follow-up check at use case integration, and the regulatory classification of the AI functionalities under the EU AI Act.
UC6-NFR-02 – Data Quality	Data quality analysis of the training dataset for completeness, consistency and relevance.	Partly validated. A data structure and processing pipeline for AI training has been set up, and quality assurance protocols for the dataset are being implemented. Pending: the formal data quality analysis on the full partner-hospital dataset.
UC6-NFR-03 – Performance	Performance testing of the AI/ML features on simulated data loads.	Pending. The AI and recommendation features run as components within the existing Well@Home environment and do not change the performance profile of the core monitoring workflows. A dedicated load test of the AI/ML features on simulated data volumes has not yet been carried out.
UC6-NFR-04 – User-friendly Interface	User satisfaction surveys with HCPs and patients.	Partly validated. The AI functionalities are delivered through interfaces that healthcare professionals and patients already use in clinical practice (Clinical Command Center, Alerts Dashboard, patient profiles, education module and the patient app), which limits the learning curve. The AI dashboard views were designed with clinical stakeholders as mockups. Pending: user satisfaction surveys with HCPs and patients during the evaluation phase.
UC6-NFR-05 – Uptime	Monitoring of system uptime metrics against the 99.9% target.	Validated. Well@Home production availability is continuously monitored as part of the platform's operational processes. The AI components are designed so that their unavailability does not interrupt the core patient monitoring and alerting workflows.
UC6-NFR-06 – Modularity	Architecture review and successful integration of at least one additional module after launch.	Validated at demonstrator level. New functionality is added as modules on top of the existing measurement and education frameworks: the Early Warning Score (EWS) was added as a new measurement type with dashboard visualisation and manual measurement workflows, and the predictive, tagging and recommendation layers are integrated as separate components. The FHIR-based interoperability backbone further allows external services and

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		partner platforms to connect without changes to the foundation.
UC6-FR-01 – Patient-centred Dashboard	Usability testing with HCPs and patients of the dashboard displaying vital parameters, trends and alerts.	Partly validated. The Clinical Command Center (CCC) and Alerts Dashboard display vital parameters, alerts and longitudinal trends, and the first AI-related visualisation was delivered on the platform. Step-based and slope-based trend visualisations are being evaluated to show values approaching clinically relevant thresholds, and the Early Warning Score is available as a measurement type in the dashboard. Pending: formal usability testing with HCPs and patients.
UC6-FR-02 – Predictive Healthcare Assistant	Human-driven and data-driven evaluation of AI predictions of potential medical conditions, against the 80% accuracy threshold from D1.2.	Pending. A first unsupervised risk-scoring model has been implemented, and the dashboard integration has been designed as mockups. Supervised models predicting elevated NCD risk, based on disease codes (ICD), are being trained on anonymised data from a partner hospital; the initial data source named in D1.2 (UZA) was replaced by another partner hospital. Pending: validation of the first NCD model against the 80% accuracy threshold, and HCP review of predictions. Predictions are displayed as risk indications, clearly separated from clinically confirmed diagnoses.
UC6-FR-03 – Prescriptive Content Labelling Assistant	HCP review of the links suggested between educational articles and medical conditions.	Partly validated. The recommendation protocol has been designed and disease-code (ICD-10) detection is working. Educational articles can be grouped into article sets that are matched to disease codes and patient tags, which the recommendation engine combines with predictive outputs and rule-based clinical guidance. Pending: implementation of the full decision rules and HCP review of the suggested links against the accuracy target from D1.2.
UC6-FR-04 – Structured Feedback Mechanism	Analysis of HCP feedback collected during pilot tests.	Partly validated. All AI-generated recommendations and educational suggestions require validation by a healthcare professional before they are shared with patients, which provides a human-in-the-loop checkpoint on every output. Pending: the structured feedback loop that feeds HCP

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		corrections back into model training, together with monitoring and explainability, and analysis of the collected feedback.
UC6-FR-05 – Semantic Interoperability of Different Data Sources	Successful data exchange between at least three systems during tests.	Validated at demonstrator level. Well@Home collects data from connected medical devices (blood glucose, heart rate, blood pressure, weight) and wearables, and third-party patient-facing applications are integrated and live in production. BeWell set up and hosts the TREAT interoperability backbone (RabbitMQ message exchange with FHIR as the clinical data format), over which Well@Home exchanges data with MyViva (Canada), Johan Sports (Netherlands) and further partner systems in the TREAT Complete demonstrator. Pending: joint closure of partner testing with the consortium.
UC6-FR-06 – Multilingual Support	Validation with test users in different language settings.	Validated. Well@Home is available to patients and HCPs in English, Dutch and French, with each release translated and reviewed through a structured translation workflow, and is used in clinical practice in these languages.
UC6-FR-07 – Personalised Education Content	Feedback from users via PROM questionnaires.	Partly validated. Patients receive assigned educational articles, measurements and notifications in the Well@Home patient app, and article sets linked to disease codes and patient tags allow content to be matched to a patient's condition. Pending: AI-assisted selection on real patient data and PROM-based user feedback.

8.2 Functional Validation

To date, functional validation with users has focused on the Clinical Command Center (CCC) and the Alerts Dashboard integrated in it, which form the clinical environment in which the AI functionalities will be delivered. BeWell held three iterative demo and feedback sessions with clinical staff and the home monitoring team at UZA. Clinicians confirmed that grouping alerts per patient makes triage clearer, that the alert lifecycle with an audit log improves accountability, and that showing alerts in the CCC and the patient profile fits their workflow. Their requests, including filtering by department and care path, sorting by priority, automatic closing of resolved missing-measurement alerts and assigning alerts to colleagues, were turned into change requests for later releases. The CCC has since been released to several hospitals and is used in testing and production, with feedback from care teams recorded continuously; this feedback led to a redesign of the measurements visualisation page and the addition of the Early Warning Score as a measurement type. A task-based comparison of two frequent monitoring tasks showed that searching

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patients by care path dropped from 58 to 11 seconds (81% less), and finding patients with out-of-bounds activity duration dropped from 1 minute 37 seconds to 18 seconds (over 80% less), compared with the legacy dashboard. Validation of the AI outputs by healthcare professionals and patients, including review of predictions and educational content links and PROM/PREM-based feedback, is planned for the remaining project period and will partly continue after the formal end of the international TREAT project.

Apart from the Clinical Command Center (CCC) dashboard, the functionalities of the Belgian demonstrator have not yet been functionally validated with user groups. Due to the delayed funding approval, the Belgian consortium started later than the international TREAT project, and its project period therefore ends later than the ITEA project. Functional validation of the remaining functionalities, including the predictive AI insights, the recommendation engine and the personalised education content, with healthcare professionals and patients is planned for this remaining Belgian project period. The absence of these results in this deliverable is therefore expected and in line with the Belgian project planning.

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9 TREAT Complete demonstrator

The TREAT Complete demonstrator is the project's integrated, cross-country demonstrator and serves as the final, ecosystem-level showcase of the TREAT project. Where the preceding demonstrators (UC1 to UC6) each present the solution of an individual consortium within its own clinical domain and platform, TREAT Complete deliberately does the opposite: it brings those individual building blocks together into a single, coherent care journey that spans multiple countries, consortium partners, and platforms.

Its purpose is to demonstrate the TREAT ecosystem as a whole, showing how independent applications, each historically operating within its own silo, can semantically interoperate to support one continuous patient journey. In doing so, the demonstrator brings together the four key innovations that the TREAT project set out to deliver, and shows them working in concert rather than in isolation:

- Integration of wearable technology: continuous capture of vital parameters and activity data through connected devices.
- Interoperability: secure, standards-based, cross-border data exchange between otherwise separate platforms.
- AI recommenders: early detection, trend analysis, and personalisation of the care journey based on real patient data.
- Engaging interfaces: professional clinical dashboards and patient-centred, conversational experiences.

To make this tangible, the demonstrator follows the fictional but realistic journey of a single patient, Maria, from early risk detection through acute telemonitoring, into long-term lifestyle management and AI-supported coaching, and finally back into clinical decision-making. Maria's story acts as the connective tissue that ties the individual consortium solutions into one narrative and makes the value of an interoperable ecosystem visible from end to end.

The demonstrator is built around two complementary goals. The first goal is to prove genuine interoperability: validating live, cross-border data exchange over the shared TREAT Interoperability Framework rather than through simulated or point-to-point connections. The second goal is to tell a coherent story: demonstrating a federated healthcare ecosystem in which diverse platforms, AI services, and wearables can dynamically plug into a seamless patient journey without re-engineering the underlying foundation. The essential characteristic being demonstrated is synergy, the idea that these innovations become substantially more powerful when orchestrated together than when used in isolation.

The final TREAT Complete demonstrator is an end-to-end, cross-country patient journey running on a shared demonstration environment, in which independent platforms exchange data live through the TREAT Interoperability Framework. It is designed to be shown as a single, closed-loop scenario, while remaining modular enough that further consortium partners can take part in the journey by pushing data in, pulling data out, or contributing a parallel branch.

The scenario centres on Maria, 62, a retired nurse who is widowed and lives alone. She stays active through weekly group walks and cycling, and while she has a high level of health literacy from her professional career, her digital literacy is low: she prefers a conversation over navigating an app. Maria has an undiagnosed underlying Type 2 Diabetes condition and, importantly, has sufficient historical medical data available in the ecosystem to enable AI-based pattern detection. The choice of a female persona is

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deliberate. Women have historically been underrepresented in clinical research, including in cardiometabolic studies, so much of the evidence behind today's risk models and care pathways rests predominantly on male data. By placing a woman at the centre of the journey, the demonstrator puts this gap in the spotlight and highlights the need for AI recommenders and care pathways that are designed, trained and evaluated on data representative of the patients they serve. Her journey transitions from acute clinical follow-up into long-term lifestyle management, which is what allows the demonstrator to exercise the full breadth of the TREAT ecosystem.

The demonstrator is structured as a six-phase journey. Each phase is anchored to a specific consortium platform and highlights one or more of the four key innovations, while the transitions between phases are where interoperability is demonstrated most explicitly.

- Phase 1: Early Signal Detection (Belgium, Well@Home). The journey begins in the Well@Home platform. The Well@Home Smart Recommender Engine analyses Maria's prior clinical history, vital-parameter trends, and risk indicators, and flags a potential underlying condition (Type 2 Diabetes). This represents clinical decision support, helping healthcare professionals identify patients who require structured follow-up. (Innovation: AI recommenders.)

- Phase 2: Acute Follow-Up via Telemonitoring (Belgium, Well@Home). A healthcare professional enrols Maria in a Diabetes Care Path. Using connected devices, Maria measures blood glucose, heart rate, blood pressure, and weight, and the data flows automatically into the platform. The care team monitors her status through the Clinical Command Center (CCC) and the Alerts Dashboard, enabling structured overview, risk stratification, and prioritised intervention. (Innovations: wearables, engaging interfaces.)

- Phase 3: Cross-Platform Data Flow (TREAT Interoperability Framework). As Maria stabilises, she is enrolled into a MyViva Diabetes Plan. The relevant vital parameters and patient context collected in Well@Home are securely transferred to MyViva across borders via the TREAT Interoperability Framework, with no duplication or manual re-entry. This transition is the first explicit demonstration of standards-based, cross-border data exchange. (Innovation: interoperability.)

- Phase 4: Lifestyle Management (Canada, MyViva). The focus shifts to long-term lifestyle management. Maria follows a structured diabetes plan in MyViva and completes journaling activities. The prior vital parameters received from Well@Home enrich her patient profile, combining clinical and behavioural insight in a single view. Her profile is enriched further with wearable and activity data provided by Johan Sports (Netherlands), which is pushed into the journey over the same interoperability framework, adding an objective view of Maria's daily activity to the clinical and self-reported picture. (Innovations: engaging interfaces, wearables.)

- Phase 5: AI-Powered Coaching (Netherlands, TU/e AI engine, and Canada, Yaro). MyViva sends Maria's vital parameters and journaling data to the AI Recommender Engine developed by TU/e. The engine analyses trends and generates personalised conversational themes and coaching prompts. These recommendations are delivered through Yaro, the virtual AR coach, which conducts a structured, engaging conversation with Maria about her health journey. (Innovations: AI recommenders, engaging interfaces.)

- Phase 6: Closing the Loop (Belgium, Well@Home). Following the coaching conversation, a structured summary report is generated and transferred back to Well@Home through the TREAT Interoperability Framework. Healthcare professionals can review the behavioural insights and

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integrate them into clinical decision-making, thereby closing the care loop between lifestyle management and clinical care. (Innovation: interoperability.)

Maria's data does not only serve the platforms that generate it. Because everything is exchanged over the shared framework in a standardised format, the same information can be made available to other consortium systems in parallel, each of which uses it in its own context. In Turkey, data from the journey is ingested into a dashboard and interpreted within an insurance setting, showing how the same interoperable data takes on additional meaning when it is given the right context. In Spain, data from the journey is consumed and analysed within a dedicated dashboarding system, offering a further analytical perspective on Maria's evolving profile. These touchpoints illustrate the central message of the demonstrator: in a connected ecosystem, the same interoperable patient data can be surfaced to the right stakeholder, in the right context, to generate the specific insight each of them needs, whether a clinician, a lifestyle coach, an insurer, or an analytical service, without any party having to own or duplicate the full dataset.

Technically, the demonstrator runs on a shared TREAT demonstration environment. The interoperability backbone that connects the participating platforms is set up and hosted by BeWell Innovations, and is based on the TREAT Interoperability Framework using a message-based exchange (RabbitMQ) with a standardised clinical data format (FHIR). Each participating consortium member exposes its contribution through its own shared demo environment, which connects to this common backbone. As long as a partner adheres to the TREAT data format, it can, in principle, take part in the journey by pushing data in or pulling data out, without changes to the foundation.

The demonstrator brings together contributions from across the consortium, each partner connecting its own platform or service into Maria's journey through the shared interoperability framework.

Partner (country)	***Contribution***
BeWell, Well@Home (Belgium)	Hosts the shared interoperability backbone; provides early detection through the Smart Recommender, acute telemonitoring via connected devices, and closes the care loop with clinical review.
MyViva (Canada)	Delivers long-term lifestyle management and journaling, and hosts the Yaro AR coach that delivers AI-driven coaching; contributes the structured summary back into the loop.
TU/e (Netherlands)	Provides the AI recommender engine and conversational logic that generate personalised coaching themes from Maria's actual patient data.
Johan Sports (Netherlands)	Provides wearable and activity data into the journey over the interoperability framework, enriching Maria's profile with objective daily-activity data.
Turkey	Ingests data from the journey into its dashboard, demonstrating how the same data is re-used interoperably and interpreted within an insurance context.

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Spain	Consumes data from the journey to analyse and visualise it within its own dashboarding system.
Portugal	Ingests data from the journey to be analysed within the Integrated Care Plan, namely device metrics.

The TREAT Complete demonstrator is provided as a shared, cross-consortium demonstration environment rather than as a single product owned by one partner. The shared interoperability backbone that connects the participating platforms is set up and hosted by BeWell Innovations, and each participating consortium member makes its contribution available through its own shared demo environment connected to that backbone.

Access is intended for controlled project, demonstration, and validation purposes within the TREAT consortium. Because the demonstrator is built on standards-based interoperability, it is also designed to remain extensible: further consortium partners can connect to the journey by following the TREAT data format and pushing data in or pulling data out, allowing the demonstrator to continue to serve as a living proof of concept for the federated TREAT ecosystem.

9.1 TREAT Concept Validation

Where the preceding demonstrators are validated against the use-case requirements defined in D1.2, TREAT Complete validates something broader: the TREAT concept itself. The central claim of the project is that wearables, interoperability, AI recommenders and engaging interfaces become substantially more valuable when they are orchestrated together within a federated ecosystem, one in which independent platforms keep their own role and data while working on a shared standard, than when each is deployed in isolation. This claim cannot be verified one requirement at a time. It can only be validated by showing the ecosystem working as a whole.

The concept is therefore validated through a live presentation of the TREAT Complete demonstrator at the ITEA final review of the TREAT project (27 November 2026). Presenting the working demonstrator to the review panel exposes the integrated ecosystem to independent, expert assessment, rather than relying solely on internal testing by the consortium. The demonstration is built around Maria, a female persona chosen deliberately to draw attention to the historical underrepresentation of women in medical research and to the importance of inclusive data for AI-driven care.

The demonstration is structured in two layers. The first layer presents the main loop: Maria's six-phase journey from early signal detection in Well@Home, through cross-border transfer to MyViva, lifestyle management and AI-supported coaching with Yaro, and back to clinical review in Well@Home. This shows that one continuous care journey can span independent platforms in Belgium, Canada and the Netherlands, with the TREAT Interoperability Framework carrying the data between them. The second layer presents each country consortium's contribution in turn. It shows how Turkey, Spain and Portugal, along with the partners in the main loop, push data into or consume data from the same journey and interpret it in their own context, whether clinical, coaching, insurance or analytical. Together, the two layers validate the defining property of a federated healthcare ecosystem: no single party owns or duplicates the full dataset, yet each stakeholder receives the information it needs, and new platforms, AI services and partners can join by adhering to the TREAT data format, without re-engineering the foundation.

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The table below summarises how each element of the TREAT concept is demonstrated and what serves as evidence during the review.

Concept element	***How it is demonstrated***	***Evidence***
TREAT Interoperability Framework	Live, message-based exchange (RabbitMQ) in a standardised clinical format (FHIR) between Well@Home and MyViva: vital parameters and patient context in Phase 3, and the structured coaching summary back to Well@Home in Phase 6.	Data exchanged live over the shared backbone hosted by BeWell Innovations, across borders, without duplication or manual re-entry.
Wearables	Connected devices capture blood glucose, heart rate, blood pressure and weight in Phase 2; wearable activity data enriches Maria's profile in Phase 4.	Measurements arrive automatically in the receiving platforms and are visible in the clinical and patient-facing views.
AI recommenders	The Well@Home Smart Recommender flags a potential Type 2 Diabetes condition in Phase 1; the TU/e AI engine generates personalised coaching themes in Phase 5; partner dashboards interpret the same data, such as the risk interpretation in the Turkish insurance context.	AI output is generated from Maria's data and visibly drives the next step in her journey: structured follow-up, a coaching conversation, or a risk insight.
Engaging interfaces	Professional dashboards in Well@Home (Clinical Command Center, Alerts Dashboard); MyViva and the Yaro AR coach for Maria; country dashboards in Turkey, Spain and Portugal.	Each stakeholder works in the interface suited to their role, including a conversational coach for a patient with low digital literacy.
Federated ecosystem (overall)	The second layer of the demonstration: Turkey, Spain and Portugal consume or contribute data from the same journey in parallel to the main loop.	The same patient data is reused in clinical, coaching, insurance and analytical contexts, with each partner connected through the TREAT data format only.

The demonstrator combines live and prepared data flows. The cross-border exchanges between Well@Home and MyViva in Phases 3 and 6 run live over the TREAT Interoperability Framework. Where a full backend integration is not needed to show the value of a contribution, such as the hand-over of the AI

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engine output to Yaro in Phase 5 and some of the country contributions, the demonstrator uses a prepared data flow based on the same TREAT data format. This keeps the focus on the clinical value and synergy of the ecosystem, while interoperability itself is proven by the live exchanges.

To keep the demonstration reliable and repeatable, it follows a pre-defined scenario with fixed inputs and expected outputs.

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